

**EPA REGISTRATION NUMBER 69268-2 – VOL. 1**

DECISION PKG. NO. 357972SUBM. DUE DATE 07-07-05SUBMISSION BAR CODE # 780391REVIEWER M TerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 332DESCRIPTOR \_\_\_\_\_ FQPA ☒ NFQPA \_\_\_\_\_☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE OF APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

06/07/0506/07/0506/09/05

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE  
☐ NOT SUBMITTED ☐ N/A☐ SUBMITTED ☐ NOT SUBMITTED  
☐ N/A

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY \_\_\_\_\_

EFFICACY \_\_\_\_\_

ACUTE TOX. \_\_\_\_\_

RASSE TOX. \_\_\_\_\_

ENVIRON. FATE \_\_\_\_\_

FISH/WILDLIFE \_\_\_\_\_

OTHER: \_\_\_\_\_

STATUS \_\_\_\_\_

RESPONSE CODE

17

RESPONSE DATE

JUN 30 2005

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 30 2005

EnviroX, LLC  
1938 E. Fairchild Street  
Danville, IL 61382

AGENT: ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

Attention: Janine Polizzi

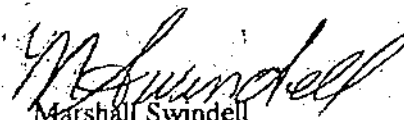
Subject: H<sub>2</sub>Orange<sub>2</sub> Concentration 117  
EPA Registration No. 69268-2  
Your Notification Dated June 7, 2005

This will acknowledge receipt of your notification to remove "or more" from the following sentences under the Directions for Use: "...when used as directed as a sanitizer, kills 99.99% from the following..." and "when used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes...", submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply:

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

### DEODORIZING

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

### CLEANING SOLUTION DILUTIONS & APPLICATIONS

#### LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

#### GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

#### HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew stains

#### SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew stains

### OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)

New! (for first 6 months only)

Registered for control of [Hepatitis B Virus]/[HBV]

Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notif: 4/18/2005, 4/25/2005, 6/07/2005

MASTER LABEL

**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**H<sub>2</sub>Orange<sub>2</sub> Concentrate 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes or more at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of cold tap water.

**CLEANING AND SANITIZING:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace mop-bucket solution daily.

**TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS:** Add 10 oz. of product concentrate per gallon of cold tap water for sinks, faucets, counters, urinals, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace mop-bucket solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES:** Add 10 ounces of product concentrate per gallon of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace mop-bucket solution daily.

**HIV-1 and HBV:** To kill HIV-1 in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon. For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS) or HBV (Hepatitis B Virus).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz/gallon and leave surfaces wet for 5 minutes.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

MASTER LABEL

**DEODORIZING**

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

**LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

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Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
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**OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)**

New! (for first 6 months only)

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Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notif: 4/18/2005, 4/25/2005, 6/07/2005

APR 26 2005

APR 26 2005

Connie Welch  
Agent for Envirox, LLC  
c/o ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

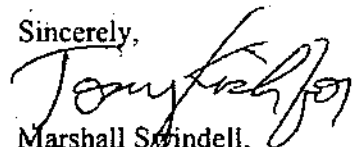
**Subject: H2Orange2 Concentrate 117**  
**EPA Reg. No. 69268-2**  
**Notification Dated 4/18/05**

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to change "Replace solution daily" with "Replace mop-bucket solution daily", to provide an additional container size of one quart, and to revise the "First Aid" statements as required by PR Notice 2001-1, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Spindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)



1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-2717  
MAIN: 703-492-0445  
FAX: 703-492-0668

E-MAIL: polizzi@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

JANINE M. POLIZZI

April 18, 2005

Document Processing Desk (NOTIF)  
U.S. Environmental Protection Agency (7504C)  
Office of Pesticide Programs  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Attn: Marshall Swindell (PM 33)

Re: H-ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2  
Notification per PR 98-10 for Other Revisions

Dear Marshall:

On behalf of our client, EnvirOx, LLC, we are submitting the enclosed notification under PR 98-10 (Section II.N) for the above product. For product stewardship purposes, we are clarifying the statement, "Replace solution daily" with "Replace mop-bucket solution daily".

In addition, we are notifying that this product will be sold in an additional container size— one quart. The labeling statements are unaffected by this change.

Finally, we have revised the First Aid Statement per PR Notice 2001-1.

Enclosed please find EPA Form 8570-1, as well as one (1) copy of the label with the revisions highlighted. Please contact me by phone or email if there are any questions or concerns about this notification.

Sincerely,

Janine Polizzi


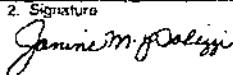
cc: EnvirOx, LLC

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**CONSULTANTS TO SUCCESS™**

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 89266-2		2. EPA Product Manager Swindel	
4. Company/Product (Name) H2Orange2 Concentrate 117		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) EnviroX, LLC 1838 E. Fairchild Street Danville, IL 61382		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address			
<b>Section II</b>			
<input type="checkbox"/> Amendment - Explain below		<input type="checkbox"/> Final printed labels in response to	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> Agency letter dated	
<input checked="" type="checkbox"/> Notification - Explain below		<input type="checkbox"/> "Me Too" Application	
		<input type="checkbox"/> Other - Explain below	
<p><b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.)          Notification of Other Revisions per PR Notice 98-10, Section II (N) and additional container size. Revise First Aid Statement per PR Notice 2001-1.</p> <p>This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.</p>			
<b>Section III</b>			
1. Material This Product Will be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
<b>Section IV</b>			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Janine M. Polizzi		Title ChemReg International, LLC	Telephone No. (Include Area Code) 703-482-2717
Certification (I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.)			B. Date Application Received  (Stamped)
2. Signature 		3. Title ChemReg International, LLC Authorized representative for EnviroX LLC	
4. Typed Name Janine Polizzi		5. Date April 18, 2005	



Janine Polizzi  
<polizzi@chemreg.com>  
05/04/2005 03:07 PM

To Tony Kish/DC/USEPA/US@EPA  
cc "Connie B. Welch" <welch@chemreg.com>  
bcc  
Subject H2ORANGE2 CONCENTRATE 117, EPA Reg. No. 69268-2

Dear Tony:

Per your request, we have updated the application and cover letter for the notification for H<sub>2</sub> ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2. The attached cover letter and application replace those that were emailed on April 25, 2005.

Thank you for your help and for revising the acceptance letter to include changes to the First Aid Statement.

<<20050404.to EPA.Cover and Application.EPA Reg. No. 69268-2.Notif.Rev. First Aid, new size, replace soln daily.pdf>>

Best wishes,

-- Janine

Janine Polizzi, M.S.  
ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

Phone: 703-492-2717

Fax: 703-492-0668

Email: [polizzi@chemreg.com](mailto:polizzi@chemreg.com) <<mailto:polizzi@chemreg.com>>

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20050404.to EPA.Cover and Application.EPA Reg. No. 69268-2.Notif.Rev. First Aid, new size, replace soln daily.pdf



Janine Polizzi  
<polizzi@chemreg.com>  
04/25/2005 04:10 PM

To: Tony Kish/DC/USEPA/US@EPA  
cc  
bcc  
Subject: H2ORANGE2 CONCENTRATE 117, EPA Reg. No. 69268-2

Dear Tony:

Per your request, we have updated the application, cover letter and label for the notification for H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2. The attached documents replace those that were hand-delivered on April 18, 2005.

Thank you for assisting us with this application.

Please contact me if you have any questions.

<<20050425.Label.EPA Reg.No. 69268-2 .Notif.clarify replace solution and rev. first aid.pdf>>

<<20050425.Cover and Application.EPA Reg.No. 69268-2.Notif.Replace Soln and Rev First Aid.pdf>>

Best regards,

-- Janine

Janine Polizzi, M.S.  
ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

Phone: 703-492-2717

Fax: 703-492-0668

Email: [polizzi@chemreg.com](mailto:polizzi@chemreg.com) <<mailto:polizzi@chemreg.com>>

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20050425.Label.EPA Reg.No. 69268-2 .Notif.clarify replace solution and rev. first aid.pdf



20050425.Cover and Application.EPA Reg.No. 69268-2.Notif.Replace Soln and Rev First Aid.pdf

MASTER LABEL

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER  
(NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR  
HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 69268-2

EPA Est. No. 69268-IL-001

Envirox, LLC  
1938 E. Fairchild St., Danville, IL 61832

### NET CONTENTS:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

MASTER LABEL

**PRECAUTIONARY STATEMENTS – HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**CAUTION.** Causes moderate eye damage. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

**FIRST AID**

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes; then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

**If swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. If in plastic bag with original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke or if in plastic bottles, triple rinse or equivalent and recycle.

Questions? Call 1-800-281-9604

# **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**H<sub>2</sub>Orange<sub>2</sub> Concentrate 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes or more at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of cold tap water.

**CLEANING AND SANITIZING:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace ~~mop-bucket~~ solution daily.

**TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS:** Add 10 oz. of product concentrate per gallon of cold tap water for sinks, faucets, counters, urinals, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace ~~mop-bucket~~ solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES:** Add 10 ounces of product concentrate per gallon of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace ~~mop-bucket~~ solution daily.

**HIV-1 and HBV:** To kill HIV-1 in 5 minutes at room temperature (20-25°C ) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C ) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon. For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS) or HBV (Hepatitis B Virus).

## **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz/gallon and leave surfaces wet for 5 minutes.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

MASTER LABEL

**DEODORIZING**

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

**LIGHT DUTY** (1 Oz / gal) GREEN (bottle or label)

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE** (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY** (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew stains

**SUPER DUTY** (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew stains

**OPTIONAL MARKETING STATEMENTS:** (one or more or none of the following may appear)

New! (for first 6 months only)

Registered for control of [Hepatitis B Virus]/[HBV]

Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notice: Clarification of statement 4/18/2005; First Aid 4/23/2005

SUBM. DUE DATE 01-23-05

REVIEWER Kleary-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE A-57

DESCRIPTOR: Amendment FOIPA X NFOIPA

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE:    ☐ CONDITIONAL    ☐ UNCONDITIONAL    ☐ RESTRICTED USE

PM RECEIVE DATE

07, 07, 04

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED  
[ ] E/A

DATE  
RETURNED

CHEMISTRY

**EFFICACY** \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ]

ACUTE TOX. \_\_\_\_\_ ] [                      ] [                      ] [

RASSE TOX. \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ]

ENVIRON. PATE \_\_\_\_\_] [\_\_\_\_\_] [\_\_\_\_\_] [\_\_\_\_\_]

FISH/WILDLIFE \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ] [ \_\_\_\_\_ ]

OTHER: \_\_\_\_\_

STATUS

RESPONSE DATE 1/13/05 ✓

24





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 13 2005

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ms. Elizabeth Anne Brown  
Regulatory Agent for,  
c/o Envirox LLC  
1990 Old Bridge Road, Suite 201  
Lake ridge, VA 22192-2383

Subject: H,Orange, Concentrate 117  
EPA Registration Number 69268-2  
Your Submission Dated November 19<sup>th</sup>, 2004  
EPA Received Dated November 19<sup>th</sup>, 2004

The amendment application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add the Hepatitis B virus to the product labeling, is acceptable.

**EFFICACY**

The submitted data (MRID Nos. 463095-01 and 463095-2) support the use of the product, H,Orange, Concentrate 117, as a virucide against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes in the presence of organic soil at a 1:12.8 dilution at room temperature.

**LABELING**

The proposed label claims that the product, H2orange2 Concentrate 117, is an effective virucide against HBV(Hepatitis B virus) in 5 minutes at room temperature at a concentration of 10 oz. product per gallon of cold temperature on inanimate, hard, non-porous surfaces. This claim is acceptable.

On page 2, under the "First Aid" instructions, change the phrase , "gentle stream on water" to read "gentle stream of water."

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510C)

25



1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

**ELIZABETH A. BROWN, PH.D.**

November 19, 2003

Mr. Marshall Swindell  
US Environmental Protection Agency  
Office of Pesticide Programs  
Antimicrobial Division  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Dear Marshall:

On behalf of our client, Envirox LLC, thank you for taking the time today to discuss with me several questions pertaining to the requirements and approaches for adding control of Hepatitis-B Virus to the labels for the 3 products registered by Envirox. This memo is to confirm our conversation and agreements.

The three products already registered are as follow:

1. H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA Reg. No. 69268-1). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan.
2. H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan.
3. H<sub>2</sub>Orange<sub>2</sub> 120 Ready to Use (EPA Reg. No. 69268-3). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Influenza A<sub>2</sub>/Japan.

In prior discussions, you raised as a potential concern whether Agency policy would allow virucidal claims with a sanitizer level registration or whether virucidal claims only could accompany a disinfectant level claim. The Agency clearly has a policy that a product can be registered as a virucide without first being registered as a disinfectant. That policy is defined in

---

**CONSULTANTS TO SUCCESS<sup>SM</sup>**

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

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Letter to M. Swindell, Nov. 19, 2003, page 2

Draft 40 CFR 156, as available on the EPA/OPP/AD website. In 156.441, virucide is separately defined from disinfectants and all other types of activity. Under 156.448 (2), it clearly is stated that a product which meets the performance standard as a virucide "but is not a disinfectant" may be registered with the appropriate limited claims. The already-registered virucidal uses of the Envirox products without disinfectant claims are clearly in line with that policy. Further, DIS/TSS-7, Efficacy Data Requirements for Virucides and the performance standards in the above 156.441 and 448 do not specify any requirement for a virucide to be a disinfectant against bacteria.

Under EPA policy and testing guidelines, the term "disinfectant" is based solely on a level of efficacy against bacteria, while "virucide" is based solely on testing against viruses. The terms are not interchangeable. A product registered as a disinfectant cannot claim virucidal activity unless all required testing for virucidal activity has been conducted and the product meets all pertinent performance standards. And there is nothing in the regulations which requires a virucidal claim to be predicated upon a disinfectant claim against bacteria. In fact, FIFRA Section 4(i)(4)(c) includes the following wording, which is not contradicted elsewhere in that law (emphasis added):

"For purposes of this subparagraph, the term "antimicrobial active ingredient" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are--

- (i) **sanitizers** intended to reduce the number of living bacteria or viable virus particles on inanimate surface or in water or air;
- (ii) **bacteriostats** intended to inhibit the growth of bacteria in the presence of moisture;
- (iii) **disinfectants** intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;
- (iv) **sterilizers** intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or
- (v) **fungicides or fungistats.**"

Thus, a pesticide product clearly can be a virucide without first having been determined to be a disinfectant.

In our discussions, you agreed that the above position is correct and that Envirox could add claims against Hepatitis-B virus to the 3 registered product labels if acceptable performance data are submitted.

You then confirmed that the appropriate testing protocol to follow to determine the efficacy against and to support addition of the claim to the labels for Hepatitis-B virus is the *in vitro* (test tube) duck assay (65 FR 51828-51830, August 25, 2000) and as appears on the EPA/OPP/AD website under Registration Policy Documents.



Letter to M. Swindell, Nov. 19, 2003, page 3

Thank you again for taking the time to discuss these issues with me and for confirming the appropriate approach. Once Envirox has developed the appropriate data, the company will submit for label amendments under the above agreements. If I have misunderstood or omitted anything from our discussions, please let me know immediately.

Regards,

Elizabeth Anne Brown

cc: Envirox, LLC

Decision Information for 69268-2			
Decision Seq: 045945	Action Code: A57, AMENDMENT, NOII FAST TRACK, 180		
FFS Start Date: 27-Jul-2004	FFS Original Decision: [ ]		
Due Date: 23-Jan-2005	FFS EUP Decision: [ ]		
ORR Target Due Dt: [ ]	FFS Sect 3 Decision: [ ]		
Registrant Response Due Date: [ ]	Start/Stop Clock: [ ] FOPA Clock: [ ]		
Current Status: PENDING (07-Jul-2004)	Days Elapsed: [ ]		
<div>Decision Ownership</div> <div>Receipts</div> <div>Data Package</div> <div>Reduced Risk</div> <div>Meetings &amp; Milestones</div> <div>FFS Information</div> <div>PAIA Negotiated Due Dates</div>			
FFS Fee Expected: \$3,000	FFS Fee Refunded: [ ]	FFS Fee Received: \$3,000	
Fee Reduction Type: [ ]	FFS Fee Reduced: [ ]		
Viewing Record 1 of 1			
Viewing Record 1 of 1			

*This documents that the  
PAIA Fee has been paid*

*Whynol  
1/13/05*

*Keep in File*

**DATA PACKAGE BEAN SHEET**

Date: 10-Dec-2004

Page 1 of 3

**\*\*\* Registration Information \*\*\***

Registration: 69268-2 - H2ORANGE2 CONCENTRATE 117

Company: 69268 - ENVIROX, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: \_\_\_\_\_

Calculated Due Date: 23-Jan-2005

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (A57) AMENDMENT;NON-FAST TRACK;

Ingredients: 000595, Hydrogen peroxide(3.95%)

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 06-Dec-2004

Due Back: \_\_\_\_\_

DP Ingredient: 000595, Hydrogen peroxide

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

**Assigned To****Date In****Date Out**

Organization: AD / PSB

07-Dec-2004

Administrative Due Date: 04-Jun-2005

Team Name: EET

07-Dec-2004

10-Dec-2004

Negotiated Due Date: \_\_\_\_\_

Reviewer Name: Wawzysko, Marcie

07-Dec-2004

10-Dec-2004

Projected Completion Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

**\*\*\* Studies Sent for Review \*\*\***

Printed on Page 2

**\*\*\* Additional Data Package for this Decision \*\*\***

Printed on Page 3

**\*\*\* Data Package Instructions \*\*\***

Please review the efficacy data supporting the proposed labeling claims (Hepatitis B virus). This data was routed to efficacy on September 8th, 2004; however, it was returned and closed out without being reviewed. This data is being submitted to efficacy again. PRIA, Action Code A57, Admin due date 01/23/2005, ETT due date 01/15/2005.

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DP#: (311285)

\*\*\* Studies Sent for Review \*\*\*

Decision#: (345946)

MRID	Citation Reference	Guideline
46309501	Ramm, K. (2004) Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus: Final Study Report: H2Orange2 Concentrate 117. Project Number: A02079, EOX01030804/DHBV/1. Unpublished study prepared by ATS Labs. 18 p.	
46309502	Miller, M. (2004) Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Duck Hepatitis B Confirmatory Assay: Final Study Report: H2Orange2 Concentrate 117. Project Number: A02078, EOX01030804/DHBV/2. Unpublished study prepared by ATS Labs. 16 p.	

DP#: (311285)

\*\*\* Additional Data Package for this Decision \*\*\*

Decision#: (345946)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	Label
305482	AD / RMB1	15-Jul-2004	23-Dec-2004	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
305482	AD / PSB	15-Jul-2004	23-Dec-2004	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No



Data Package Information for O: 345848: 69268-2: A57: AMENDMENT (NON-FAST TRACK)

DP Sequence: 311285
Expedite: ☐ Yes ☒ No
Label: ☒ Yes ☐ No
CSF: ☒ Yes ☐ No

Bean Count: 1
Data Package Title:
Data Package Type:

Unlock Data Pkg
Bean Sheet

Instructions: Please review the efficacy data supporting the proposed labeling claims (Hepatitis B virus). This data was routed to efficacy on September 8th, 2004; however, it was returned and closed out without being reviewed. This data is being submitted to efficacy again. PRIA, Action Code A57, Admin due date 01/23/2005, ETT due date 01/15/2005.

Sent To:
Sent From:
DP Dates:
MRDS:
Sub-DP:
DP Ingredients:
DP Contract:
Receipts:

Data Package Comments:
Waiver/Documentation:

Comment:
Primary and confirmatory studies against DBHV were acceptable under Agency guidelines. Product is a sanitizer with virucidal claims, this has been previously approved.

Viewing Record 1 of 1

69268-2

03/14/2002

1/4

FRONT PANEL - /ENVIROX 117

MASTER LABEL

03-11-02

(logo)

**H<sub>2</sub>ORANGE, CONCENTRATE 117**

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

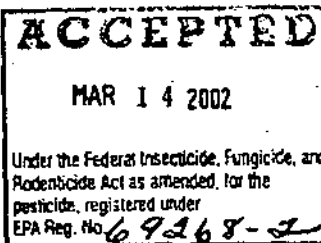
**CAUTION**

## PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2  
EPA Est. No. 69268-IL-001

ENVIROX, LLC.  
1938 E. FAIRCHILD ST  
DANVILLE, IL 61832



NET CONTENTS: 5 gal (640 oz); 1 gal (128 oz, 3784 ml); 32 oz (946 ml)

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**Caution.** Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

**FIRST AID**

**IF IN EYES:** Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

**DIRECTIONS FOR USE**

*It is violation of Federal law to use this product in a manner inconsistent with its labeling.*

**H<sub>2</sub>Orange, Concentrate 117**, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **H<sub>2</sub>Orange, Concentrate 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**ACCEPTED**

MAR 14 2002

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 69268-2

3/4

BACK PANEL - ENVIROX 117

MASTER LABEL

03-11-02  
EnviOx 800-281-9604

**Cleaning:** Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**HIV-1:** To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange, Concentrate 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

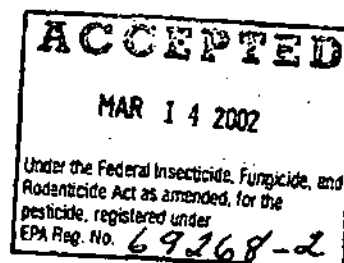
**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy Duty or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

**Deodorizing**

For general deodorizing, use 2 part H<sub>2</sub>Orange, Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange, Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter, smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.



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**CLEANING SOLUTION DILUTIONS & APPLICATIONS****LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS****CLEANING APPLICATIONS****Bathroom surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min. then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

**Kitchen surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes then scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

**Carpet stains**

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for 5 to 10 min. Blot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution (24-48 oz/gal) and rinse with clean water.

**Glass surfaces**

USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not necessary to polish the surface dry.

**Laundry pre-spray**

USE SUPER DUTY DILUTION (24-48 oz/gal). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., then launder or scrub and rinse as usual.

**Tough soils**

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let sit a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.

**ACCEPTED**

MAR 14 2002

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 69268-2

## Elizabeth Brown

**From:** Elizabeth Brown  
**Sent:** Thursday, July 15, 2004 1:45 PM  
**To:** 'leavy.karen@epa.gov'  
**Subject:** EPA Reg. No. 69268-2

Karen:

On behalf of our client, Envirox LLC, and as requested in your phone call of Tuesday, July 13, attached please find as pdf files the following items:

- Data matrix (Agency File and Public Use Copies) updated to show the assigned MRIDs for the data submitted in support of the pending amendment for this product
- Certification with Respect to Citation of Data

Please confirm receipt of these items, and please don't hesitate to let me know if you have any questions or need anything further.

Regards,  
Elizabeth



20040713.Data matrix Concentra... 20040713.Data matrix Concentra... 20040714.Cert wrt data citatio...

Elizabeth Anne Brown, Ph.D.  
Director, Scientific & Regulatory Affairs  
ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

Phone: 703-492-7905  
Fax: 703-492-0668  
Email: brown@chemreg.com

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7/19/2004

Karen - I've not yet had confirmation of receipt from you, so here's a hard copy.

Elizabeth



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: July 13, 2004

EPA Reg No / File Symbol 69268-2

Page 1 of 1

Applicant's/Registrant's Name and Address: Envirox, LLC  
1938 E. Fairchild Street  
P.O. Box 2327  
Danville, IL 61834

Product: H<sub>2</sub>Ox Orange Concentrate 117

Ingredient: Hydrogen Peroxide

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.20 61-1 to -3	Product Chemistry	44532001	Envirox, LLC	Own	69268-1
158.20 62-1 to -3	Product Chemistry	44532001	Envirox, LLC	Own	69268-1
158.20 63-2 to -21	Product Chemistry	44532001	Envirox, LLC	Own	69268-1
158.135 81-1 to 81-6	Toxicology	44532004	Envirox, LLC	PL	
158.20 Efficacy	AOAC Sanitizer Test	44532002	Envirox, LLC	Own	69268-1
158.20 Efficacy	HIV Virucidal Test	44532003	Envirox, LLC	Own	69268-1
158.20 Efficacy	Virucidal effectiveness	44560101	Envirox, LLC	Own	69268-1
158.20 61-1 to -3	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
158.20 62-1 to -3	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
158.20 63-2 to -21	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
OPPTS 810.2100	Virucidal efficacy (HBV)	46309501 46309502	Envirox, LLC	Own	69268-2

Signature

*Elizabeth Anne Brown*

Name and Title

Elizabeth Anne Brown  
ChemReg International, Agent for Envirox LLC

Date

7/13/2004



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: July 13, 2004	EPA Reg No./ File Symbol 69268-2	Page 1 of 1
Applicant's/Registrant's Name and Address: Envirox, LLC 1938 E. Fairchild Street P.O. Box 2327 Danville, IL 61834	Product: H <sub>2</sub> Orange <sub>2</sub> Concentrate 117	
Ingredient: Hydrogen Peroxide		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Envirox, LLC	Own	69268-1
			Envirox, LLC	Own	69268-1
			Envirox, LLC	Own	69268-1
			Envirox, LLC	PL	
			Envirox, LLC	Own	69268-1
			Envirox, LLC	Own	69268-1
			Envirox, LLC	Own	69268-1
			Envirox, LLC	Own	69268-2
			Envirox, LLC	Own	69268-2
			Envirox, LLC	Own	69268-2
			Envirox, LLC	Own	69268-2

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown ChemReg International, Agent for Envirox LLC	Date 7/13/2004
--	--	-------------------





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M STREET, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Envirox, LLC 1938 E. Fairchild Street P.O. Box 2327 Danville, IL 61834 217-442-8596	EPA Registration Number/File Symbol 69268-2
Active Ingredient(s) and/or representative test compound(s) Hydrogen peroxide	Date July 14, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name H <sub>2</sub> Oxange Concentrate 117

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature <i>Elizabeth Anne Brown</i>	Date 7/14/2004	Typed or Printed Name and Title Elizabeth Anne Brown ChemReg International, LLC, Agent for Envirox, LLC
--	-------------------	---

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 10, 2004

**MEMORANDUM**

**Subject:** Efficacy Review for H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, EPA Reg. No. 69268-2;  
DP Barcode: D311285

**From:** Marcie Wawzysko, Microbiologist *Marcie Wawzysko*  
Product Science Branch  
Antimicrobials Division (7510C) *12/10/04*

**Thru:** Nancy Whyte, Acting Team Leader *Nancy Whyte*  
Product Science Branch  
Antimicrobials Division (7510C) *December 10, 2004*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

**To:** Marshall Swindell PM 33 / Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

**Applicant:** Envirox, LLC  
1938 E. Fairchild Street  
P.O. Box 2327  
Danville, IL 61832

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Hydrogen Peroxide.....	3.95%
<u>Other ingredients</u> .....	96.05%
Total.....	100.00%

## **I. BACKGROUND**

The product, H<sub>2</sub>Orange<sub>2</sub> 117, is an Agency registered non-food contact sanitizer and virucide for use on hard, non-porous surfaces. The applicant wishes to add claims to the product for Hepatitis B virus, and has submitted data to support this claim. Studies were conducted by ATS Labs, located at 1285 Corporate Center Drive, Suite 110 in Eagan MN 55121.

The data package contained a letter from the applicant's representative to the Agency (dated November 19, 2003), Agency form 8570-4 (Confidential Statement of Formula), the last accepted label (dated March 14, 2002), the proposed label, and two studies (MRIDS 463095-01 and 463095-02) with Statements of No Data Confidentiality and Good Laboratory Practice for both.

## **II. USE DIRECTIONS**

The product is designed for use as a non-food contact surface sanitizer and virucide for hard, non-porous surfaces such as sinks, faucets, counters, urinals, toilets, walls, stalls, and floors. The proposed label gives the following instructions for the use of the product as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

The proposed label also gives instructions for cleaning and decontaminating against Hepatitis B virus and HIV-1, and for deodorizing. The label also states that "This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that..."

## **III. AGENCY STANDARDS FOR PROPOSED CLAIMS**

### **Virucides**

The effectiveness of virucides must be tested using virological techniques that simulate the conditions under which the product is intended for use. For products with intended use on dry, inanimate environmental surfaces, carrier tests that are variations of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal Spray Products Test (for surface spray disinfectants) must be used to produce virucidal data. The virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10<sup>4</sup> from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus must be assayed by an appropriate virological technique testing a minimum of four determinations for each dilution. The protocol for the viral assay must include viral recovery, cytotoxicity controls, and ID-50 values. Test results should be reported as the

reduction of the virus titer by the activity of the germicide (ID-50 of the virus control less the ID-50 of the test system) expressed as  $\log_{10}$  and calculated by a statistical method. For virucidal data to be acceptable, the product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results. Separate studies on two batches of product are required for each virus. These Agency standards are presented in DIS/TSS-7.

#### **Virucides – Novel Virus Protocol Standards**

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory). The validation of a protocol requires the use of a common positive control disinfectant to be tested concurrently with all new products. For the Hepatitis B Virus protocol, the usual control is BTC-835, a quaternary ammonium compound product obtained from Stepan Company. This agent serves as both an intra-laboratory and an inter-laboratory control and is used for analyzing the reproducibility of the efficacy data results for the protocol. These Agency standards are tailored from those presented in the Federal Register, Vol. 65, No. 166, Friday, August 25, 2000.

#### **IV. SUMMARY OF SUBMITTED STUDIES**

**1. MRID 463095-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus" for H<sub>2</sub>Orange<sub>2</sub> 117 by Karen M. Ramm. Study conducted by ATS Labs, Project Number A02079. Study completed June 24, 2004.**

This study, under the direction of Karen M. Ramm, was conducted against duck Hepatitis B virus (DHBV16 strain, obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (obtained from AppTec Laboratory Services, St. Paul, MN). The study followed ATS Labs protocol number EOX01030804.DHBV.1. Two lots (Lot Nos. 98804 and 98763) were tested. A use dilution of 10oz. product per gallon of sterilized deionized tap water was created (a 3100 ppm dilution). 100% duck serum was present in the viral stock as the organic soil load. Films of the virus were made by spreading 0.2 mL of the viral inoculum over the bottoms of ten sterile glass petri dishes. Viral films were dried for 30 minutes at 20.0°C in 45% relative humidity. For each lot of the product, dried viral films were exposed to 2.0 mL of the use dilution for 5 minutes at 20.0°C. The virus/test agent mixture was immediately passed through Sephadex gel columns to detoxify. The filtrate (considered at 10<sup>-1</sup> dilution) was again passed through a Sephadex column then serially diluted in Leibovitz L-15 medium with 0.1% glucose, 10µM dexamethasone, 10µg/mL insulin, 20mM HEPES, 10µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 mL of each dilution and incubated for viral absorption overnight at 36-38°C and 5-7% CO<sub>2</sub>. Post absorption, 3.0 mL of Leibovitz L-15 medium was added to each cell culture well and cultures were incubated for ten days at 36-38°C and 5-7% CO<sub>2</sub>. Cultures were then scored for cytotoxicity and cells were fixed with ethanol. Plates were assayed by

indirect immunofluorescence assay. Controls included those for cytotoxicity, neutralization, virus stock titer, and plate recovery. Stepan Company's BTC 835 was used as the data consistency control at two concentrations, 175 and 350 ppm. The TCID<sub>50</sub> was calculated by method of Spearman Karber.

Note: Applicant included data from a failed test (conducted May 7, 2004) due to bacterial contamination of the indicator cell cultures.

**2. MRID 463095-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Duck Hepatitis B Confirmatory Assay" for H<sub>2</sub>Orange<sub>2</sub> 117 by Mary J. Miller. Study conducted by ATS Labs, Project Number A02078. Study completed May 18, 2004.**

This study, under the direction of Mary J. Miller, was conducted against duck Hepatitis B virus (DHBV16 strain, obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (obtained from AppTec Laboratory Services, St. Paul, MN). The study followed ATS Labs protocol number EOX01030804.DHBV.2. One lot (Lot No. 98804) was tested. A use dilution of 10oz. product per gallon of sterilized deionized tap water was created (a 3100 ppm dilution). 100% duck serum was present in the viral stock as the organic soil load. Films of the virus were made by spreading 0.2 mL of the viral inoculum over the bottoms of eight sterile glass petri dishes. Viral films were dried for 30 minutes at 20.1°C in 45% relative humidity. Dried viral films were exposed to 2.0 mL of the use dilution for 5 minutes at 20.1°C. The virus/test agent mixture was immediately passed through Sephadex gel columns to detoxify. The filtrate (considered at 10<sup>-1</sup> dilution) was again passed through a Sephadex column then serially diluted in Leibovitz L-15 medium with 0.1% glucose, 10µM dexamethasone, 10µg/mL insulin, 20mM HEPES, 10µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 mL of each dilution and incubated for viral absorption overnight at 36-38°C and 2-7% CO<sub>2</sub>. Post absorption, 3.0 mL of Leibovitz L-15 medium was added to each cell culture well and cultures were incubated for ten days at 36-38°C and 2-7% CO<sub>2</sub>. Cultures were then scored for cytotoxicity and cells were fixed with ethanol. Plates were assayed by indirect immunofluorescence assay. Controls included those for cytotoxicity, neutralization, virus stock titer, and plate recovery. Stepan Company's BTC 835 was used as the data consistency control at two concentrations, 175 and 350 ppm. The TCID<sub>50</sub> was calculated by method of Spearman Karber.

## V. RESULTS

MRID Number	Organism	Results			Plate Recovery Control (TCID <sub>50</sub> /mL)
			Lot No. 98804	Lot No. 98763	
463095-01	Duck Hepatitis B virus	10 <sup>-2</sup> to 10 <sup>-4</sup> dilutions	Complete inactivation	Complete inactivation	10 <sup>5.0</sup>
		TCID <sub>50</sub> /mL	≤10 <sup>1.5</sup>	≤10 <sup>1.5</sup>	
463095-02	Duck Hepatitis B virus	10 <sup>-2</sup> to 10 <sup>-4</sup> dilutions	Complete inactivation	—	10 <sup>5.5</sup>
		TCID <sub>50</sub> /mL	≤10 <sup>1.5</sup>	—	

## VI. CONCLUSIONS

The submitted data (MRID Nos. 463095-01 and 463095-02) **support** the use of the product, H<sub>2</sub>Orange<sub>2</sub> 117 as a virucide against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes in the presence of organic soil at a 1:12.8 dilution at room temperature. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested for virucidal efficacy. Based on the plate recovery control, it appears that a recoverable virus titer of at least 10<sup>4</sup> was achieved. Study controls met the criteria for a valid test.

## VII. RECOMMENDATIONS

1. The proposed label claims that the product, H<sub>2</sub>Orange<sub>2</sub> 117, is an effective virucide against HBV (Hepatitis B virus) in 5 minutes at room temperature at a concentration of 10oz. product per gallon of cold tap water on inanimate, hard, non-porous surfaces. This claim is **acceptable**.
2. The following change needs to be made to the proposed label on page 2, under First Aid instructions, change "gentle stream o water" to read "gentle stream of water."

DECISION PKG. NO.

351212

FORM. DUE DATE

11/25/04

SUBMISSION BAR CODE #

770640

REVIEWER

TK

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO.

69268-2

PM

33

ACTION CODE

362

DESCRIPTOR

Revised CSF

FQPA X

NFQPA

☐ CHILD RESISTANT PACKAGING:☐ REQUIRED☐ NOT REQUIRED

REGISTRATION TYPE:

☐ CONDITIONAL☐ UNCONDITIONAL☐ RESTRICTED USE

DATE ON APPLICATION

10/26/04

EPA RECEIVE DATE

10/26/04

PM RECEIVE DATE

11/17/04

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SELECTIVE☐ SUBMITTED☐ NOT SUBMITTED☐ NOT SUBMITTED☐ N/A☐ N/A

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

ACUTE TOX.

RASEE TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER:

STATUS

Revised CSF was 7/29/98

RESPONSE CODE

17

RESPONSE DATE

NOV 30 2004

51

NOV 8 2004

Elizabeth Brown, Agent for Envirox  
c/o Chem Reg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

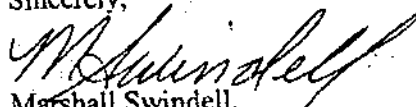
**Subject: H2Orange2 Concentrate 117**  
**EPA Reg. No. 69268-2**  
**Your Notification Dated 10/26/04**

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised basic Confidential Statement of Formula (CSF), and a new alternate CSF, both dated 10/20/04, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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United States  
Environmental Protection Agency

Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 69268-2	2. EPA Product Manager Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H2Orange2 Concentrate 117	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox, LLC 1938 E. Fairchild Street Danville, IL 61382	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Agency letter dated "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)  
Notification of Change in Product Chemistry per PR Notice 98-10, Section III

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
<b>*Certification must be submitted</b>				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product: <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Elizabeth Anne Brown	Title ChemReg International, LLC	Telephone No. (Include Area Code) 703-492-7905
------------------------------	-------------------------------------	---

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

2. Signature

3. Title  
ChemReg International, LLC  
Authorized representative for Envirox LLC

4. Typed Name  
Elizabeth Anne Brown

5. Date  
October 26, 2004

6. Date Application Received

.....  
(Stamped)

.....  
.....  
.....

# ChemReg

INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 26, 2004

*Contains Confidential Business Information*

Document Processing Desk (NOTIF)  
U.S. Environmental Protection Agency (7505C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Attn: Marshall Swindell (PM 33)

Re: H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2  
Notification per PR 98-10 for Changes in Product Chemistry

Dear Marshall:

On behalf of our client, EnvirOx, LLC, and as discussed with you by phone on Wednesday, October 20, 2004, we are submitting the enclosed notification under PR 98-10 for product chemistry changes for the above product.

The previously accepted CSF was dated 7/29/98 and was accepted by the Agency on 10/23/98. Corrections have been made to the basic confidential statement of formula, and an alternate confidential statement of formula is being submitted at this time. As you specifically directed, these are being submitted as notifications, and I have enclosed an unsigned but detailed commented version of each CSF to clearly identify the corrections and revisions as you requested.

Enclosed please find EPA Form 8570-1, two copies each of the basic and alternate CSF, and one copy each of commented versions of the basic and alternate CSF. Please contact me by phone or email if there are any questions or concerns about this notification. Because of the extent of the corrections, I would appreciate receiving confirmation of the acceptability of this notification by email when the Agency has completed its review.

Sincerely,



Elizabeth Anne Brown

cc: EnvirOx, LLC

CONSULTANTS TO SUCCESS<sup>SM</sup>

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

16 A 8.2

*Cricket*

July 7, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-345946  
EPA File Symbol or Registration Number: 69268-2  
Product Name: H2ORANGE2 CONCENTRATE 117  
EPA Receipt Date: 06-Jul-2004  
EPA Company Number: 69268  
Company Name: ENVIROX, LLC

ELIZABETH ANNE BROWN  
ENVIROX, LLC  
C/O CHEMREG INTERNATIONAL, LLC  
1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VA 22192-2383

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A57

AMENDMENT;NON-FAST TRACK;

Please remit payment in the amount of: \$ 3,000 to:

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

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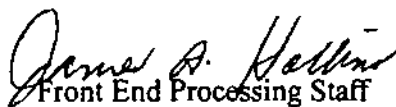
By Courier:  
U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely,

  
James A. Heltner  
Front End Processing Staff

Information Resources and Services Division

## Fee for Service

This package includes the following

for Division

☐ New FFS Action

☐ RD

☒ Amendment

☒ AD

☐ Waiver Request

☐ BPPD

☐ Voluntary Payment Request

Receipt Nos. S- 763349

Product/Risk Manager: Pm 33

EPA File Symbol/Reg. No. 69268-2

Pin-Punch Date: 7/6/04

☐ This item is NOT subject to FFS action.

Action Code: A57

Amount Due: \$ 3000

Voluntary Payment Reduction Amount:

☐ 0%

☐ 40%

☐ 80%

Original Decision #:

☐ 10%

☐ 50%

☐ 90%

☐ 20%

☐ 60%

☐ 100%

☐ 25%

☐ 70%

☐ Other

D- \_\_\_\_\_

☐ 30%

☐ 75%

\_\_\_\_\_%

Reviewer: Lantz/Noble

Date: 7/7/04

Remarks: Review of Efficacy Data

**DATA PACKAGE BEAN SHEET**

Date: 15-Jul-2004

Page 1 of 1

**\*\*\* Registration Information \*\*\***

Registration: 69268-2 - H2ORANGE2 CONCENTRATE 117

Company: 69268 - ENVIROX, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: \_\_\_\_\_ Calculated Due Date: 23-Jan-2005

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (A57) AMENDMENT;NON-FAST TRACK;

Ingredients: 000595, Hydrogen peroxide(3.95%)

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 15-Jul-2004

Due Back: \_\_\_\_\_

DP Ingredient: 000595, Hydrogen peroxide

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

**Assigned To****Date In****Date Out**

Organization: AD / PSB

Administrative Due Date: 11-Jan-2005

Team Name: EET

Negotiated Due Date: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_

Projected Completion Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

**\*\*\* Studies Sent for Review \*\*\***

No Studies

**\*\*\* Additional Data Package for this Decision \*\*\***

No Additional Data Packages

**\*\*\* Data Package Instructions \*\*\***

PLEASE REVIEW THE EFFICACY DATA SUPPORTING THE PROPOSED LABELING CLAIM  
(HEPATITIS B VIRUS).  
FEE FOR SERVICE, ACTION CODE A57, ADMIN DUE DATE 01-23-2005, ETT DUE DATE,  
12-23-2004.

58



United States  
**Environmental Protection Agency**  
 Office of Pesticide Programs (7505C)  
 Washington, DC 20460

42 B7-2

### Notice of Supplemental Distribution of a Registered Pesticide Product

#### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

69268-2

Distributor Company Number

73835

**Note: Do not submit distributor product labels**

Name of Registered Product (basic product name accepted by EPA)

H2Orange2 Concentrate 117  
 (Manual Dilution)

Distributor Product Name 1. H2Orange2 Concentrate 117 for Manual Dilution.

2. H2Orange2 Concentrate 117 for Manual Dilutions. 3. H2Orange2 Concentrate 117 for Manual Dilution Only

Name and Address of Distributor (Type; include ZIP code)

Performance Food Group  
 12500 Westcreek Parkway  
 Richmond, VA. 23220

#### Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by...", or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

#### Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

*Raymond J. B.*

Date

7/20/03

#### Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

*M. Rebecca P. ...*

Date

7/15/03

59



United States  
Environmental Protection Agency  
Office of Pesticide Programs (7505C)  
Washington, DC 20460

42 B2-2

# Notice of Supplemental Distribution of a Registered Pesticide Product

## Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product  
69268-2

Distributor Company Number  
73835

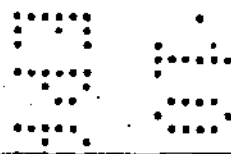
**Note: Do not submit distributor product labels**

Name of Registered Product (basic product name accepted by EPA)  
H2Orange2 Concentrate 117  
(Manual Dilution)

Distributor Product Name  
1. H2Orange2 Concentrate 117 for Manual Dilution.  
2. H2Orange2 Concentrate 117 for Manual and Dispenser Dilutions.

Name and Address of Distributor (Type; include ZIP code)

Performance Food Group  
12500 Westcreek Parkway  
Richmond, VA 23220



## Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by...", or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

## Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice:

Signature and Title of Distributor

Date

Raymond J. B. Category manager

6/08/03

## Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

Dr. Valerie Venturini Spec VP

6/6/03 60



SUBMISSION BAR CODE 5612584 REVIEWER KLeary-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 332

DESCRIPTOR Alternate Brand Name

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION--  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

05 20 02

05 21 02

05 23 02

METHOD OF SUPPORT:

FORMULATORS EXEMPTION

[ ] CITE ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER


STATUS

RESPONSE CODE 17

RESPONSE DATE

JUN 19 2002

✓ 61



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUN 19 2002

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ms. Janine Polizzi  
Agent for,  
EnvirOX, LLC  
1938 E. Fairchild Street

Subject: H2Orange2 Concentrate 117  
EPA Registration Number 69268-2  
Your Notification Dated May 20<sup>th</sup>, 2002  
EPA Received Date May 21<sup>st</sup>, 2002

Dear Ms. Polizzi:

This notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the alternate brand name, H2Orange2 Concentrated Household Cleaner, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Swindell".

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510C)

602

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

<div style="display: inline-block; text-align: center;">             United States  <b>Environmental Protection Agency</b>              Washington, DC 20460           </div>		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide – Section I</b>			
1. Company/Product Number 69268-2		2. EPA Product Manager M. Swindell	
4. Company/Product (Name) H <sub>2</sub> Orange <sub>2</sub> Concentrate 117		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Envirox, LLC 1938 E. Fairchild Street Danville, IL 61832 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment – Explain below		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application	
<input checked="" type="checkbox"/> Notification – Explain below		<input type="checkbox"/> Other – Explain below	
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.) This is a Notification per PR Notice 98-10 to add an Alternate Brand Name, H <sub>2</sub> Orange <sub>2</sub> Concentrated Household Cleaner. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
<b>Section III</b>			
1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
<b>*Certification must be submitted</b>		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 ounces	5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____
<b>Section IV</b>			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Janine M. Polizzi		Title ChemReg International, LLC Authorized Agent	Telephone No. (include Area Code) 703-492-2717
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="border: 1px solid black; padding: 5px; text-align: center;">           (Stamped)         </div>	
2. Signature 		3. Title ChemReg International, LLC Authorized Agent	
4. Typed Name Janine M. Polizzi		5. Date May 20, 2002	



1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-2717  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: polizzi@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

JANINE M. POLIZZI

May 20, 2002

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

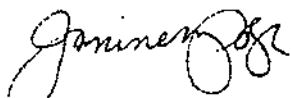
Attn: Mr. Marshall Swindell (PM 33)

Re: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2)  
Notification per PR 98-10 to add alternate brand name, H<sub>2</sub>Orange<sub>2</sub> Concentrated  
Household Cleaner

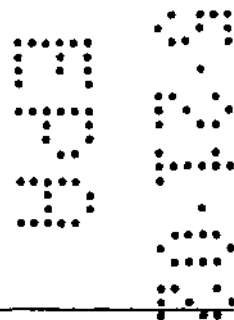
Dear Mr. Swindell:

As permitted under PR Notice 98-10, EnvirOx, LLC is adding an alternate brand name, H<sub>2</sub>Orange<sub>2</sub> Concentrated Household Cleaner, to EPA Reg. No. 69268-2. Enclosed please find EPA Form 8570-1 and one (1) copy of the label with the change identified. Please let me know whether you have any questions about this notification, which is submitted on behalf of our client, EnvirOx, LLC.

Regards,

  
Janine M. Polizzi

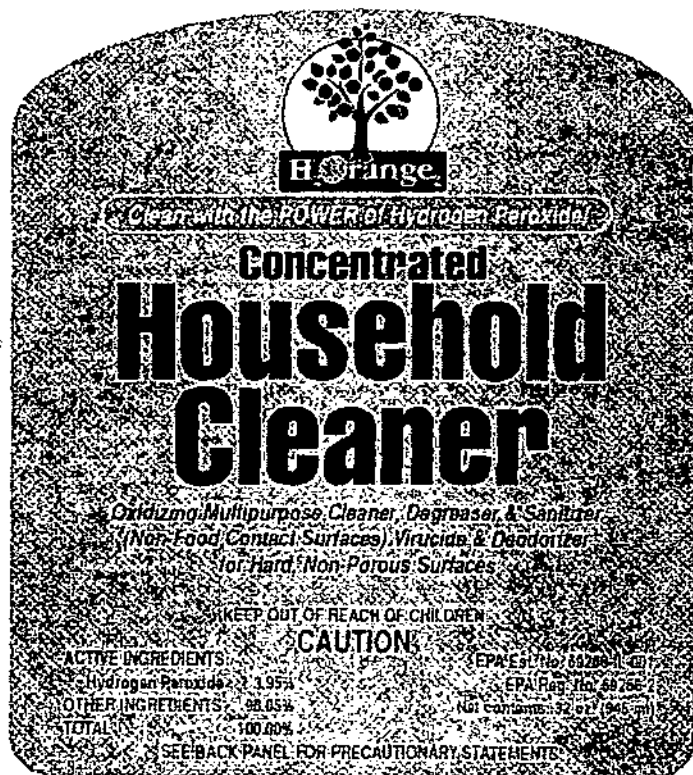
cc: EnvirOx, LLC



CONSULTANTS TO SUCCESS™

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

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## CONCENTRATE

## DIRECTIONS FOR USE It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Envirox H-Orange, Concentrated Household Cleaner**, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, H-Orange, Concentrated Household Cleaner kills the following viruses in 5 minutes at room temperature (20-21°C): Herpes simplex virus Type 2, Influenza A2/Japan. To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**CLEANING:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, toilets, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**DEODORIZING:** For general deodorizing, use 2 parts H-Orange, Concentrated Household Cleaner to 126 parts water (2 oz./gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors due to spillage from post-occlusion, post-detonation dressing and bag changes, and other spills such as urine or fecal matter, smoke or soot deposits, industrial plant processes, mildew and mold surfaces in musty closets. For effective, high level, deodorizing, use 10 parts H-Orange, Concentrated Household Cleaner to 118 parts water (10 oz./gallon).

**TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

## CLEANING DILUTIONS

## CLEANING APPLICATIONS

## Bathroom surfaces

**USE HEAVY-DUTY DILUTION.** (10 oz./gal.) Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for five minutes then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let dry.

## Kitchen surfaces

**USE HEAVY-DUTY DILUTION.** (10 oz./gal.) Spray and wipe clean. For heavy soils on hood and stove tops, spray and let sit a few minutes then scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

## Carpet stains

**USE CARPET SPOTTER DILUTION.** (2 oz./gal.) Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for five to ten minutes. Blot the spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution (24-48 oz./gal.) and rinse with clean water.

## Glass surfaces

**USE LIGHT-DUTY DILUTION.** (1 oz./gal.) Spray surface and wipe clean. It is not necessary to polish the surface dry.

## Laundry pre-spray

**USE SUPER-DUTY DILUTION.** (24-48 oz./gal.) Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least fifteen minutes, then launder or scrub and rinse as usual.

## Tough soils

**USE SUPER-DUTY DILUTION.** (24-48 oz./gal.) Spray the soil, let sit a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue, and pet soils.

## PRECAUTIONARY STATEMENTS—HAZARDS TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Causes moderate eye damage. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

## FIRST AID:

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN AND CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Note to Physicians: Probable ocular damage may contraindicate the use of gastric lavage.

## STORAGE AND DISPOSAL:

**IN CASE OF SPILL:** Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE:** Do not contaminate water, food or feed by storage. Store below 60°F. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

Manufactured by Envirox L.L.C. • Danville, Illinois • 800-281-9804

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 332

DESCRIPTOR Label Change

[ ] CHILD RESISTANT PACKAGING:	[ ] CERTIFICATION
	[ ] NON-RESIDENTIAL USE ONLY
	[ ] NOT APPLICABLE

REGISTRATION TYPE:    ☐ CONDITIONAL        ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE:

PM RECEIVE DATE-

03	11	02
----	----	----

03	11	02
----	----	----

0.3	13	02
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~~METHOD OF SUPPORT~~

~~FORMULATORS: EXEMPTION~~

( ) CITE-ALL  
( ) SELECTIVE  
( ) NOT SUBMITTED  
( ) NOT APPLICABLE  
( ) INCORRECT/RESUB.

[ ]	SUBMITTED
[ ]	NOT SUBMITTED
[ ]	NOT APPLICABLE
[ ]	INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT-

**DUE  
DATE**

DATE -  
RETURNED

CHEMISTRY

## EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE 17

RESPONSE DATE

APR 04 2002

66

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 04 2002

Kyle Sibinovic, Agent for Envirox  
c/o Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

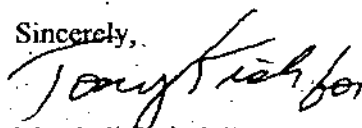
Subject: H2Orange2 Concentrate 117  
EPA Reg. No. 69268-2  
Your Notification Dated 3/11/2001

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to change the registrants address, telephone, and fax, and to add the alternate brand name "H2Orange2 Concentrated Household Cleaner", and to change abbreviate the container sizes from gallon to gal, and ounce to oz, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

## CONCURRENCES

SYMBOL							
SURNAME							
DATE							

33

**SHALDRA, INC.**  
**4327 REELS MILL RD - FREDERICK, MD 21704-7759**  
**(301) 695-1200 FAX: (301) 695-1409**  
**email: shaldra@starpower.net**

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
US Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501 for

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch I  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: H2Orange2 117 Concentrate  
Notification of Address Correction  
EPA Reg. No. 69268-2  
OPP ID# 233388  
03-11-2002

Dear Mr. Swindell:

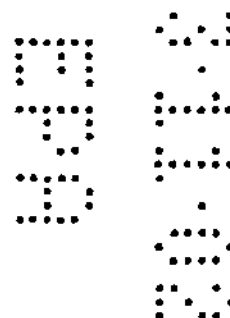
As directed, I am sending you the following notification:

1. Application for Notification of Address Correction - OPP ID # 233388.  
(a) Notification of the address correction for Envirox, LLC  
From: Envirox, LLC To: Envirox, LLC New phone #: 217-442-8596  
Box 19-Maple Grove Rd. 1938 E. Fairchild St. New fax #: 217-442-2568  
Georgetown, IL 61842 Danville, IL 61832  
(b) Addition of the alternate brand name: H<sub>2</sub>Orange<sub>2</sub> Concentrated Household Cleaner.  
(c) Change container sizes to read: gal in place of gallon, oz in place of ounce.
2. Copy of the master label with the address correction noted.
3. All correspondence is to be sent as usual to the above address to the attention of our agent, Dr. Kyle H. Sibinovic, at her address as given above.

The above correction is the only change made to the label. Except for item 1(c), no other changes have been made since the changes to the First Aid section submitted in October, 2001, and the notification statement as per PR Notice 98-10 is included on the Form 8570-1.

Sincerely yours,

*Kyle H. Sibinovic*  
Kyle H. Sibinovic, Ph.D.  
Agent for Envirox, LLC







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☒ Other

OPP Identifier Number  
**233388**

### Application for Pesticide - Section I

1. Company/Product Number <b>69268-2</b>	2. EPA Product Manager <b>Mr. Sumrell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>H2 Orange 117 Concentrate</b>	PM# <b>33</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Envy LLC 1938 Fairchild St Danville IL 61832</b> <input type="checkbox"/> Check if this is a new address	6. Expedited Review In accordance with FIFRA Section 3(c)(3) (b)(i) my product is similar or identical in composition and labeling to EPA Reg. No. _____ Product Name _____	

### Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below. <b>Address change</b> <b>Alternate Brand Name</b>	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II) This notification is consistent with provision 45-2, 48-10 + EPA Reg. 40 CFR 152.46, and no other change has been made to the labeling or CSF. This product. I understand that it is a violation of 18 USC 1001 to willfully make any false statement to EPA. I further understand that if the notification is not consistent with section 45-2, 48-10 + 40 CFR 152.46, this product may be in violation of FIFRA + I may be subject to enforcement action + penalties under Sec 12 + 12.5 FIFRA Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

### Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>Kyle H. S. Binovic, PhD</b>	Title <b>Agent</b>	Telephone No. (Include Area Code) <b>301.695.7200</b>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			Date Application Received (Stamped) _____
2. Signature <b>[Signature]</b>	3. Title <b>Agent</b>		
4. Typed Name <b>Kyle H. S. Binovic, PhD</b>	5. Date <b>03-01-02</b>	69	

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, enduse reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4)).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Formulator's Exemption Statement (EPA Form 8570-27).
4. Five copies of draft labeling.
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A:** Check the appropriate action for which you are submitting this form.

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point):** This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, etc., reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

70-1221

FRONT PANEL - /ENVIROX 117

MASTER LABEL

03-11-02

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

**OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES**

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

**KEEP OUT OF REACH OF CHILDREN**

### **CAUTION**

#### **PRECAUTIONARY STATEMENTS**

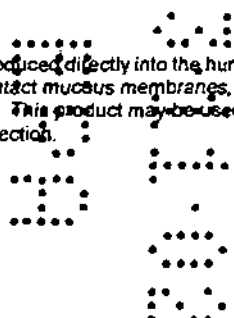
**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 69268-2  
EPA Est. No. 69268-IL-001

**ENVIROX, LLC.**  
**1938 E. FAIRCHILD ST**  
**DANVILLE, IL 61832**

**NET CONTENTS: 5 gal (640 oz); 1 gal (128 oz, 3784 ml); 32 oz(946 ml)**

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



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**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**Caution.** Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

***After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.***

**FIRST AID**

**IF IN EYES:** Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

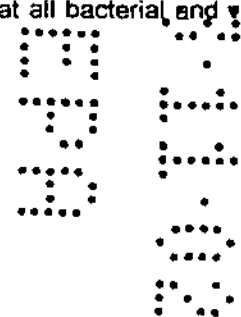
**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**H<sub>2</sub>Orange, Concentrate 117**, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **H<sub>2</sub>Orange, Concentrate 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.



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**Cleaning:** Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**HIV-1:** To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy Duty or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

**Deodorizing**

For general deodorizing, use 2 part H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

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**CLEANING SOLUTION DILUTIONS & APPLICATIONS****LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS****CLEANING APPLICATIONS****Bathroom surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min. then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

**Kitchen surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes then scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

**Carpet stains**

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for 5 to 10 min. Blot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution(24-48 oz/gal) and rinse with clean water.

**Glass surfaces**

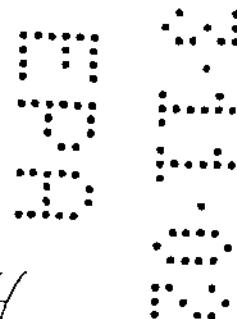
USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not necessary to polish the surface dry.

**Laundry pre-spray**

USE SUPER DUTY DILUTION (24-48 oz/gal). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., then launder or scrub and rinse as usual.

**Tough soils**

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let sit a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.



Reviewer ID

P. Jenkins

Submission No.

5612099

Data Package No.

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 69268-2 PM 33Action Code 302

|10| Descriptor (Amend/Resubmissions only)

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging

☐ (C) Certification☐ (S) Service Person

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☐ (N) Not Classified

|35| Date on Application: |04| EPA Received Date:

|0|3|11|02|  
MO DAY YR|0|3|12|02|  
MO DAY YR

|40| Date Received by PM

|0|3|12|02|  
MO DAY YR

|80| Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission☐ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

DATE  
SENTDUE  
DATEDATE  
RETURNEDRESPONSE  
CODERESPONSE  
DATE

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

|115| FINAL Response  
ACTION Code17

|120| Response

MAR 14 2002

MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No

75

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 14 2002

Shaldra, Inc., Agent for  
**EnvirOx, LLC**  
 c/o 4327 Reels Mill Road  
 Frederick, MD 21704-7759

Attention: Kyle H. Sibinovic, PhD

Subject: **H<sub>2</sub> Orange<sub>2</sub> Concentrate 117**  
 EPA Registration No. 69268-2  
 Amendment Application Dated: March 1, 2002  
 EPA Received Date: February 8, 2002

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely,



Marshall Swindell  
 Product Manager (33)  
 Regulatory Management Branch I  
 Antimicrobials Division (7510C)

Enclosure

76

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



FRONT PANEL - /ENVIROX 117

MASTER LABEL

03-11-02

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

**OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES**

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

**KEEP OUT OF REACH OF CHILDREN**

### **CAUTION**

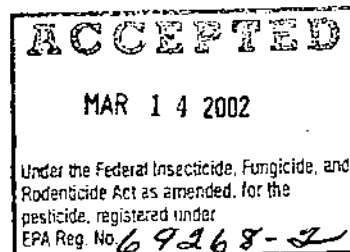
#### **PRECAUTIONARY STATEMENTS**

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 69268-2  
EPA Est. No. 69268-IL-001

**ENVIROX, LLC.  
1938 E. FAIRCHILD ST  
DANVILLE, IL 61832**

**NET CONTENTS: 5 gal (640 oz); 1 gal (128 oz, 3784 ml); 32 oz(946 ml)**



This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**Caution.** Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

**After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.**

**FIRST AID**

**IF IN EYES:** Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

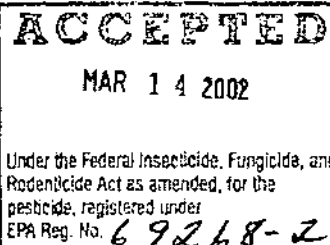
**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**H<sub>2</sub>Orange, Concentrate 117**, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **H<sub>2</sub>Orange, Concentrate 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.



**Cleaning:** Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

**HIV-1:** To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange, Concentrate 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

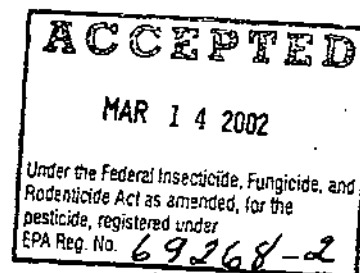
**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy Duty or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

**Deodorizing**

For general deodorizing, use 2 part H<sub>2</sub>Orange, Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange, Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter, smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.



**CLEANING SOLUTION DILUTIONS & APPLICATIONS****LIGHT DUTY** (1 Oz / gal) **GREEN** (bottle or label)

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE** (2 Oz / gal) **BLUE** (bottle or label)

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY** (10 Oz / gal) **RED** (bottle or label)

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY** (24-48 Oz / gal) **PURPLE** (bottle or label)

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS****CLEANING APPLICATIONS****Bathroom surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min. then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

**Kitchen surfaces**

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes then scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

**Carpet stains**

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for 5 to 10 min. Blot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution(24-48 oz/gal) and rinse with clean water.

**Glass surfaces**

USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not necessary to polish the surface dry.

**Laundry pre-spray**

USE SUPER DUTY DILUTION (24-48 oz/gal). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., then launder or scrub and rinse as usual.

**Tough soils**

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let sit a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.

**ACCEPTED**

MAR 14 2002

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 69268-2

5612099

**SHALDRA, INC.**  
**4327 REELS MILL RD - FREDERICK, MD 21704-7759**  
**(301) 695-1200 FAX: (301) 695-1409**  
**email: shaldra@starpower.net**

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch I  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Copies of EnvirOx labels for: H2Orange2  
117 Concentrate (5 copies each) with  
correct address on label for stamping.  
EPA Reg. # 69268-2  
03-11-2002

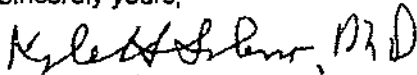
Dear Mr. Swindell:

Following are 5 copies of the above referenced label with the correct address of EnvirOx, LLC on the first page. The states are requesting that we obtain a stamped label from your office with this address correction on it to accompany the state applications.

We greatly appreciate your providing us with the needed stamped labels for that use.

Thank you for your assistance with this matter.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for EnvirOx, LLC

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number  
**233388**

**Application for Pesticide - Section I**

1. Company/Product Number <b>69268-2</b>	2. EPA Product Manager <b>Mr. Surnell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) <b>W. Orange 2117 Concentrate</b>	PM# <b>33</b>	
4. Name and Address of Applicant (Include ZIP Code) <b>Enviro LLC 1938 Fairchild St Danville, IL 61832</b>		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below. <b>Address change</b> <b>Alternate Brand Name</b>	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) This notification is consistent with provisions of 45-2, 98-10, 40 CFR 152.46, and no other than have been made to the labeling of CSF of this product. I understand that it is a violation of 18 USC 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with terms 45-2, 98-10, 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action + penalties under Section 12 of FIFRA Section - III

**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>Kyle H Sibmovic, PhD</b>	Title <b>Agent</b>	Telephone No. (Include Area Code) <b>301 6951200</b>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)  <b>82</b>
2. Signature <b>[Signature]</b>	3. Title <b>Agent</b>		
4. Typed Name <b>Kyle H Sibmovic, PhD</b>	5. Date <b>03-01-02</b>		

FQPA

SUBMISSION BAR CODE # 5579-347

REVIEWER K. Leary-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 333

DESCRIPTOR Alternate Grand Name

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

04 27 00

04 28 00

05 01 00

METHOD OF SUPPORT

FORMULATORS-EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER


STATUS

RESPONSE CODE

17

RESPONSE DATE

MAY 09 2000

83

252074 37 B1-2

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved. OMB No. 2070-0044. Approval Expires 1-31-86



United States  
Environmental Protection Agency  
Office of Pesticide Programs (7505C)  
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product  
69288-2 6

Distributor Company Number  
73635 1

Note: Do not submit distributor product labels

Name of Registered Product (Basic product name accepted by EPA)  
H2 Orange 2 117 (Manual Dilution)

Distributor Product Name  
H2 Orange 2 117 (Manual Dilution)

Name and Address of Distributor (Type; include ZIP code)

PERFORMANCE FOOD GROUP  
12500 WESTCREEK PARKWAY  
RICHMOND, VA 23220

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by...", or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

*Raymond J. Brown* Chemical Category Manager June 18, 2001

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

*Kyle M. Schumacher, Agent* June 22, 2001

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

6-25-2001

WHE - EPA

84





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAY 09 2000

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

Attention: Kyle H. Sibinovic

Subject: H<sub>2</sub> Orange<sub>2</sub> Concentrate 117  
EPA Registration Number 69268-2  
Your Submission Dated April 27<sup>th</sup>, 2000  
EPA Received Date April 28<sup>th</sup>, 2000

This will acknowledge receipt of your notification to add the alternate brand name "H<sub>2</sub> Orange<sub>2</sub> 117 (Manuel Dilution)" submitted under the provisions of FIFRA section 3(c)9. based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marshall Swindell".

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7505C)

95

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409  
email: shaldra@starpower.net

Marshall Swindell  
Product Manager Team 33  
Regulatory Management Branch I  
Antimicrobial Program Division (7510C)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Notification of Alternate Brand Name for Product  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233362  
Response to letter of 04-05-2000  
04-27-2000

Dear Mr. Swindell:

Enclosed please find the following:

1. Transmittal letter.
2. Application for Pesticide Notification - OPP ID # 233362, for the addition of alternate brand name, with notification statement.

To be consistent with the wishes of the State of California, the sponsor, EnvirOx, LLC, wishes to add the alternate brand name for this product of: H<sub>2</sub>Orange<sub>2</sub> 117 (Manual Dilution).

This notification is filed in accordance with PR Notice 95-2, Section II. A.1, and is consistent with 98-10. As it is apparent that the initial submission in which the notification statement was attached as a separate page and was apparently lost, the notification statement is located on form 8570-1.

Thank you for your attention to this notification.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*

Kyle H. Sibinovic, Ph.D.  
Agent for EnvirOx, LLC

86

86



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number  
233362

## Application for Pesticide - Section I

1. Company/Product Number 69268-1	2. EPA Product Manager Mr. M. S. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H2O range 2 Concentrate 117	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Enduro, LLC PO Box 19, Maple Grove Rd Georgetown, IL 61846 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below. Alt brand name H2O range 2 117 (Manual Ductum)	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
This notification is consistent with provisions of 40 CFR 152.46 and no other changes have been made to the labeling of H2O range 2 product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the notification is not consistent with the terms of 40 CFR 152.46, the notification product may be in violation of FIFRA and may be subject to enforcement action penalties under Section 12(a)(1)(A) of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kyle H. Simoni, PhD	Title Agent	Telephone No. (Include Area Code) 301-655-1200
2. Signature [Signature]		3. Title Agent
4. Typed Name Kyle H. Simoni, PhD		5. Date 04-27-00
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped) 8-7

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

### PAPERWORK REDUCTION ACT NOTICE:

Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2138), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4)).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Formulator's Exemption Statement (EPA Form 8570-27).
4. Five copies of draft labeling.
5. Three copies of any data submitted.
6. Authorization letter where applicable.
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A - Check the appropriate section for which you are submitting this form.**

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)", "amend the Confidential Statement of Formula by:", "reregistration submission", "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point):** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too", reregistration, etc.

1. Self-explanatory.
6. EPA Use Only.

FQPA

SUBMISSION BAR CODE # 5577409REVIEWER K. Brady-MunkCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 332DESCRIPTOR Alternate Brand Name

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
 [ ] NON-RESIDENTIAL USE ONLY  
 [ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

03 16 0003 17 0003 20 00

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
 [ ] SELECTIVE  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

[ ] SUBMITTED  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER \_\_\_\_\_

STATUS \_\_\_\_\_

RESPONSE CODE 10

RESPONSE DATE

APR 5 2000 ✓

89



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

APR 5 2000

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Shaldra, Inc.  
4327 Reeds Mill Road  
Frederick, MD 21704-7759

Attention: Kyle H. Sibinovic, Ph.D.

Subject: H<sub>2</sub> Orange<sub>2</sub> Concentrate 117  
EPA Registration Number 69268-2  
Your Submission Dated March 16, 2000  
EPA Received Date March 17, 2000

This is to acknowledge receipt of your notification to add the additional brand name of H<sub>2</sub> Orange<sub>2</sub> 117. This notification is unacceptable due to the omission of the notification statement as per PR Notice 98-10 and EPA regulations 40CFR 152.46.

Resubmit a revised EPA form 8570-1 in which the appropriate notification statement as per PR Notice 98-10 appears in Section II under the subheading "Explanation".

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script that reads "Marshall Swindell".

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division (7505C)

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409  
email: shaldra@starpower.net

Marshall Swindell  
Product Manager Team 33  
Regulatory Management Branch I  
Antimicrobial Program Division (7510C)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Notification of Alternate Brand Name for Product  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233357  
03-16-2000

Dear Mr. Swindell:

Enclosed please find the following:

1. Transmittal letter.
2. Application for Pesticide Notification - OPP ID # 233357, for the addition of alternate brand name.

To be consistent with the wishes of the State of California, the sponsor, EnvirOx, LLC, wishes to add the alternate brand name for this product of: H<sub>2</sub>Orange<sub>2</sub> 117 (Manuel Dilution).

This notification is filed in accordance with PR Notice 95-2, Section II. A.1.

Thank you for your attention to this notification.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*

Kyle H. Sibinovic, Ph.D.  
Agent for EnvirOx, LLC

03  
16  
2000

91



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

233357

## Application for Pesticide - Section I

1. Company/Product Number 69268-2	2. EPA Product Manager Mr. Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H2Orange 2 Concentrate 117	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox, LLC Maple Grove Rd Georgetown, IL 61846 <input type="checkbox"/> Check if this is a new address	5. Expedited Review: In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Addition of Alternate Brand Name of  
H2Orange 2 117 (manual Dilution)

## Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Water Soluble Packaging wgt. _____ No. per container _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kyle H. Siodinovic, PhD	Title Agent	Telephone No. (Include Area Code) 301-625-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Kyle H. Siodinovic, PhD	3. Title Agent	 92
4. Typed Name Kyle H. Siodinovic, PhD	5. Date 03-16-00	



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

### PAPERWORK REDUCTION ACT NOTICE

Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2138), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). If not exempted by 40 CFR 152.81 (b) (4);
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A:** Check the appropriate action for which you are submitting this form.

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3(B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)", "amend the Confidential Statement of Formula by", "reregistration submission", "general label revision of use directions". Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point):** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too" reregistration, etc.

1. Self-explanatory.
2. EPA Use Only.

FQPA

SUBMISSION BAR CODE # 5567180REVIEWER T KishCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 307DESCRIPTOR Tox. Data & Revised Labeling

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

08	03	99
----	----	----

08	06	99
----	----	----

08	09	99
----	----	----

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

1/31/2000TK

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 31 2000

Alphen LLC  
P. O. Box 19  
Maple Grove Road  
Georgetown, IL 61846

Mailed To: Kyle Sibinovic, Agent For Alphen, Inc.  
Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

RE: EPA Reg. No. 69268-2  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
Your Amendment Dated 8/3/99

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to submit four new acute toxicology studies in support of a change of the Signal Word from "DANGER" to "CAUTION", is acceptable, providing that you make the following label changes listed in this letter.

A copy of the label stamped "Accepted With Comments" is enclosed for your records.

**SIGNAL WORD CHANGE APPROVAL BASIS**

This product, and the companion product (EPA Reg. No. 69268-1), were originally registered based on the "Cite All" method of support. Thus, product specific acute toxicology studies were never submitted or reviewed for either product. The "Signal Word", "Precautionary Statements", and "Statement of Practical Treatment" for both products were originally assigned based on the "Peroxy Compounds" RED, and similar "Me Too" registered products.

The four acute toxicology studies you submitted with your Amendment are acceptable (see attached reviews) and apply to both EPA Reg. No. 69268-1 (8% hydrogen peroxide), and EPA Reg. No. 69268-2 (4% hydrogen peroxide). The test substance used was the formula for EPA Reg. No. 69268-1 (8% hydrogen peroxide). The acute toxicology categories for this product, and for the EPA Reg. No. 69268-1 are as follows:

Oral - 3, MRID 44892603, acceptable  
Dermal - 3, MRID 44892604, acceptable  
Inhalation - 3, Assigned pending contrary data, no MRID ever submitted/cited  
Eye - 3, MRID 44892601, acceptable  
Skin - 4, MRID 44892602, acceptable

Sensitization - Not a sensitizer pending contrary data, no MRID ever submitted/cited

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

**LABEL CHANGES**

You must submit five copies of a revised final label which incorporates the following changes. Because the newly established acute toxicology categories above apply to both EPA Reg. No.'s 69268-1 and 69268-2, **you should also submit an Amendment for EPA Reg. No. 69268-1 requesting a change of the "Signal Word" and other label changes listed below.** Please include a copy of this letter with your submission.

**Required Label Changes**

1. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Precautionary Statements" to read exactly as follows.

**"Caution.** Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling."

2. Delete the sentence, "Product, after dilution according to directions, is non-irritating."

3. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Statement of Practical treatment" to read in the following order, exactly as follows using boldface and caps.

**"IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

**"IF ON SKIN:** Wash with plenty of soap and water. Get medical attention."

**"IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol."

**"IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

**Note To Physician:** Probable mucosal damage may contraindicate the use of gastric lavage."

4. Delete the sentence, "In case of contact with product concentrate."

5. On page 3 of the label, the word "officier" is misspelled.

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CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

907

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

FRONT PANEL - ALPHEN 117

MASTER LABEL

04-30-99

(logo)

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

### CAUTION

#### PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 31 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

EPA Reg. No. 069268-2  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**Caution.** ~~Undiluted product concentrate~~ Causes moderate eye damage. Avoid contact with eyes, on skin or clothing. Avoid contamination of food. Wash thoroughly with soap and water after handling.

**Product, after dilution according to directions, is non-irritating.**

**STATEMENT OF PRACTICAL TREATMENT**

**In case of CONTACT with product concentrate**

**If in eyes:** Flush immediately with plenty of cold water. Remove contact lenses. Get medical attention if irritation persists.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention if irritation occurs and persists.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

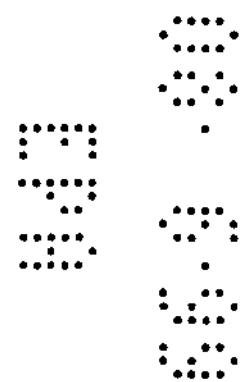
**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 31 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25° C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

**Deodorizing**

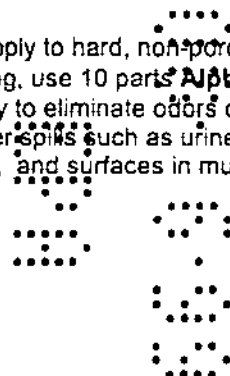
For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 31 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

**LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

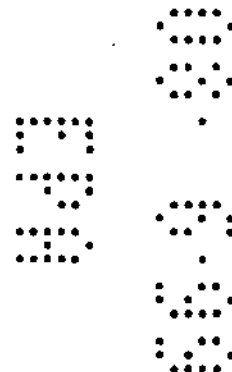
Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 31 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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AUG 17 1999

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

ALPHEN, INC.  
P.O. BOX 19  
GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/06/99. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Marshall Swindell  
Product Manager PM33  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

448926-00

Re: Resubmission and Submission Toxicology results with  
label change for product H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233358  
08-03-1999

Dear Mr. Swindell:

Enclosed please find the following:

1. Transmittal letter.
2. Application for Pesticide Notification - OPP ID # 233358.
3. Certification with Respect to Citation of Data.
3. Formulator's Exemption Form.
4. Copy of the matrix for this product.
5. Three copies each of the following volumes:

Volume I: Acute Eye Irritation in Rabbits (resubmission) 44892601

Volume II: Acute Dermal Irritation in Rabbits (resubmission) 44892602

Volume III: Acute Oral Toxicity/LD50 in Rats (new) 44892603

Volume IV: Acute Dermal Toxicity in Rabbits/LD 50 in rabbits. (new) 44892604
6. Five (5) copies of amended label.

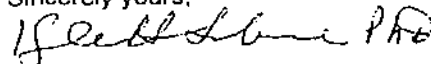
Volumes I and II were originally submitted on 04-30-1999, but are apparently missing as they did not reach your section. Volumes III and IV are copies of studies currently under review in California as part of Alphen's submission to that state. As recommended by Mr. Kish, we are submitting all four studies at this time.

The results of the eye irritation studies (Volume I) clearly permit the modification of the label Signal Word to CAUTION as the product falls in Category III. The sponsor wishes to amend the label for this product as given in the attached five label copies. The dermal irritation study using the more concentrated product, H<sub>2</sub>Orange 2 Super Concentrate 112, showed the product was not a dermal irritant. Therefore, this product would fall into Category IV for Dermal Irritation, but the sponsor proposes to maintain the Category III wording.

We would appreciate your prompt review of these studies. The sponsor will have to print new labels for this product and would like to use the new wording for the precautionary statements and Signal word at that time.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number. Thank you for your attention to this submission.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, LLC

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number  
**233358**

### Application for Pesticide - Section I

1. Company/Product Number <b>692-68-2</b>	2. EPA Product Manager <b>Mr. Swinfall</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product Name <b>H<sub>2</sub>O Orange 2 Concentrate 117</b>	PM# <b>53</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Alphen, LLC P.O. Box 19 - Maple Grove Rd. Georgetown, IL 61846</b> <input type="checkbox"/> Check if this is a new address.	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

*Resubmission Acute eye irritation + Acute dermal irritation  
Submission Acute Oral and Acute Dermal  
Appl. to change signal word to Caution*

### Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Notification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product: <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

### Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>Kyle H. Sibinovic, PhD</b>	Title <b>Agent</b>	Telephone No. (include Area Code) <b>301-695-1200</b>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)          <b>104</b>
2. Signature <i>[Signature]</i>	3. Title <b>Agent</b>		
4. Typed Name <b>Kyle H. Sibinovic, PhD</b>	5. Date <b>08-03-99</b>		

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product.

(Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by"; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information)** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** - This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-1759  
(301) 695-1200 - FAX (301) 695-1409

Marshall Swindell  
Product Manager PM33  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Submission Toxicology results with request for label  
change for product H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233355  
04-30-1999

Dear Mr. Swindell:

Enclosed please find the following:

1. Transmittal letter.
2. Application for Pesticide Notification - OPP ID # 233355.
3. Certification with Respect to Citation of Data.
3. Formulator's Exemption Form.
4. Copy of the matrix for this product.
5. Three copies each of the following volumes:  
Volume I: Acute Eye Irritation in Rabbits.  
Volume II: Acute Dermal Irritation in Rabbits
6. Five (5) copies of amended label.

The results of the eye irritation studies (Volume I) clearly permit the modification of the label Signal Word to CAUTION as the product falls in Category III. The sponsor wishes to amend the label for this product as given in the attached five label copies. The dermal irritation study using the more concentrated product, H<sub>2</sub>Orange 2 Super Concentrate 112, showed the product was not a dermal irritant. Therefore, this product would fall into Category IV for Dermal Irritation, but the sponsor proposes to maintain the Category III wording.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number.

Thank you for your attention to this submission.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, LLC



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

 401 M Street, S.W.  
 WASHINGTON, D.C. 20460

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## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Alphen, LLC P.O. Box 19-Maple Grove Rd. Georgetown, IL 61846 301-695-1200	EPA Registration Number/File Symbol 69268-2
Active Ingredient(s) and/or representative test compound(s) Hydrogen Peroxide	Date 04-30-99
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) 1 Step Degreaser, sanitizer, virucide and deodorizer for hard surfaces	Product Name H2Orange2 Concentrate 117

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to fill out this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input checked="" type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
---	--

## SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, this form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature Kyle H. Sibinovic, PhD	Date 04-30-99	Typed or Printed Name and Title Kyle H. Sibinovic, PhD, Agent
-------------------------------------	------------------	--

United States Environmental Protection Agency  
Washington, DC 20460

## Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address

Alpha, LLC  
PO Box 19 - Maple Grove Rd  
Georgetown, IL 61846

EPA File Symbol/Registration Number

69268-2

Product Name

H<sub>2</sub>O Orange 2 Concentrate 17

Date of Confidential Statement of Formula (EPA Form 8570-4)

04-29-98

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Hydrogen Peroxide [REDACTED]	[REDACTED]	

\*Product ingredient source information may be entitled to confidential treatment\*

Signature

Name and Title

Kyle H. S. binovic, PhD  
Agent

Date

04-30-98





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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## DATA MATRIX

EPA Reg No./File Symbol 69268-2		Page 1 of 1			
Applicant's Registrant's Name & Address Alphen, LLC P.O. Box 19- Maple Grove Road, Georgetown, IL 61846		Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.20 61-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 112
158.20 62-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	69268-1
158.20 63-2 to 21	Product Chemistry	44532001	Alphen, Inc.	own	69268-1
158-135 81-1 to 6	Toxicology	44532004	OEL Criteria Document	PL	
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	own	69268-1
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	own	69268-1
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own	69268-1
158.20 61-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-2
158.20 62-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-2
158.20 63-2 to 21	Product Chemistry	44582301	Alphen, Inc.	own	69268-2
Signature <i>Kyle H. Sibinovic</i>		Name and Title Kyle H. Sibinovic, Ph.D., Agent		Date 04-30-99	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved, OMB No. 2070-0060

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DATA MATRIX

Date 04-30-99		EPA Reg No./File Symbol 69268-		Page 1 of 1	
Applicant's/Registrant's Name & Address Alphen, Inc., A Div. of Dynachem P.O. Box 19 - Maple Grove Road, Georgetown, IL 61846		Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Alphen, Inc.	Own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 117
			Alphen, Inc.	own	69268-1
			Alphen, Inc.	own	69268-1
			Alphen, Inc.	own	69268-1
			OEL Criteria Document	own	
			Alphen, Inc.	own	69268-1
			Alphen, Inc.	own	69268-1
			Alphen, Inc.	own	69268-1
			Alphen, Inc.	own	69268-2
			Alphen, Inc.	own	69268-2
			Alphen, Inc.	own	69268-2
Signature <i>Kyle H. Sibinovic</i>			Name and Title Kyle H. Sibinovic, Ph.D., Agent		Date 04-30-99



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

01/21/00

MEMORANDUM

Subject: D258938  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Registration No. 69268-2

From: Wallace Powell, Biologist *John D. Powell*  
Product Science Branch *01-21-00*  
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader  
Chemistry/Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C) *K. P. Hicks*  
*1/21/00*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

To: Marshall Swindell, Product Manager, Team 33  
Tony Kish, Team Reviewer, Team 33  
Regulatory Management Branch  
Antimicrobials Division (7510C)

BACKGROUND

The registrant, Alphen, Inc. (as represented by an agent), has submitted studies for primary eye irritation, primary dermal irritation, acute oral toxicity, and acute dermal toxicity - MRID No<sup>s</sup>. 448926-01 through 448926-04, respectively. The studies were submitted in support of a registration amendment for H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, EPA Registration No. 69268-2, a hard-surface treatment product containing hydrogen peroxide as the active ingredient at 3.95% of the formulation by weight. The registrant wishes to revise the human-hazard and practical-treatment statements on the product label and to change the Signal Word from DANGER to CAUTION. The submitted studies were initially reviewed for Product Science Branch (PSB) by Oak Ridge National Laboratory. The reviews are attached to this memorandum.

RECOMMENDATION

The submitted studies are acceptable. PSB concurs with the acute Toxicity Categories listed below which were determined in the attached study reviews.

<u>Acute effect</u>	<u>Category</u>
Acute oral toxicity	III - LD <sub>50</sub> > 2000 mg/kg; this indicates Category III or IV. Category III is assigned for regulatory purposes.
Acute dermal tox.	III - This limit test indicates Category III or IV. Category III is assigned for regulatory purposes.
Primary eye irritation	III
Primary dermal irrit.	IV

The registrant selected H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA Registration No. 69268-1) as the test material for the dermal irritation, acute oral, and acute dermal toxicity studies. This is acceptable, since that product is more concentrated but otherwise similar to the subject product, and tested out to be non-irritating (Category IV) to the skin and only moderately acutely toxic (Category III) orally and dermally.

The above list of acute Toxicity Categories for the product is incomplete, lacking any reference to acute inhalation or dermal sensitization data or waivers. However, neither the EPA-accepted product label nor the new proposed label nor the registrant's 08/03/99 correspondence makes any reference to inhalation or sensitization. Therefore, the submitted studies are not being reviewed here as a proposed complete data set, but only as support for the label revisions.

PRODUCT LABELING

The following comments apply, in regard to the proposed label of EPA Received date 08/06/99:

1. In the human hazards section, the registrant should delete the statement, "Product, after dilution according to directions, is non-irritating." The phrase "Undiluted product concentrate" should also be deleted from the statement, "Undiluted product concentrate causes moderate eye damage," because the phrase can be taken to imply that the use-dilution is harmless.

Even though the use-dilution proposed for sanitization is 1:32 by volume, the above text cannot be accepted in the absence of an eye irritation study on the dilution. The results of the submitted eye study on the concentrate are cause for concern. The reason that an eye irritation hazard level as mild as Category III can be assigned to the study is that the observed problems at Day 3 (72 hours) cleared before the Day 7 observation. The problems, however, were significant

and might have persisted at comparable levels for a considerable time after Day 3 (in the absence of further observations recorded before Day 7).

2. In the Practical Treatment section, the registrant should delete the phrase "with product concentrate" from the heading, "In case of CONTACT with product concentrate." No data were submitted or cited to support the concept that the use-dilutions need no practical-treatment statements. Category IV's would have to be assigned across-the-board in order for the full heading to be acceptable.
3. The statements required in the Agency's *Label Review Manual* for the human-hazards section are as follows:

Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Therefore, the following revision (at a minimum) is necessary:

Add the statement, "Harmful if swallowed or absorbed through skin."

4. The proposed "If swallowed" statements for practical treatment are not the statements indicated by the Agency's *Label Review Manual* for the proposed product. However, ingestion practical-treatment is a controversial topic, and the registrant's proposed statements can be accepted if the registrant considers them to be medically appropriate, and if the registrant adds to them an instruction to "call a physician or poison control center," or to "get medical attention."

DATA EVALUATION REPORT

**HYDROGEN PEROXIDE**  
(ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 112)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (81-1)  
MRID 44892603; DP BARCODE: 258938

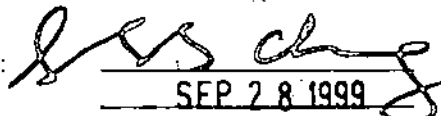
Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202


Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K116


Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: SEP 28 1999

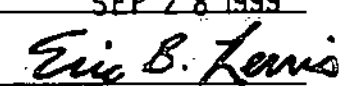
Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature:   
Date: SEP 28 1999

Robert H. Ross, M.S., Group Leader

Signature:   
Date: SEP 28 1999

Quality Assurance:  
Eric Lewis, M.S.

Signature:   
Date: SEP 28 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

HYDROGEN PEROXIDE

Acute Oral Study (81-1)

EPA Reviewer: Wallace Powell, Ph.D. *W Powell*

, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Acute Oral Toxicity - Rat  
OPPTS 870.1100 [§81-1]

DP BARCODE: D258938

SUBMISSION CODE: S567180

P.C. CODE: 000595

CASE NO.: 062401

TEST MATERIAL: Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide)

SYNONYMS: not reported

CITATION: Graver, K. (1999) Acute oral toxicity/LD50 in rats. MB Research Laboratories, 1765 Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 99-7513.01, June 25, 1999. MRID 44892603. Unpublished.

SPONSOR: Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44892603) five male and five female fasted young adult Wistar rats per group were given a single oral 2000 mg/kg (Limit test) dose of Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide, Batch No. 97334) by gavage and observed for 14 days.

No animals died during the study. Chromorrhinorhea, wet anogenital area, emaciation, few feces, nose/mouth area stained red, lethargy, flaccidity, ataxia, diarrhea, soiling of the anogenital area, and/or dyspnea were noted on some of the rats. All rats had normal body weight gains. Mottled kidneys were noted in two males and two females at necropsy.

The oral LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg (Limit test).

Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III based on the LD<sub>50</sub>.

This acute oral study is classified as **Acceptable/guideline** and satisfies the Subdivision F guideline requirements for an acute oral study (81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

A. MATERIALS1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 112

Description: clear light yellow liquid

Lot/Batch #: 97334

Specific gravity: 1.04

Composition: not reported

2. Vehicle and/or positive control

None

3. Test animals

Species: rat

Strain: Wistar

Age and/or weight at dosing: approximately 7-13 weeks; males: 210-235 g, females: 212-233 g

Source: Ace Animals, Boyertown, PA

Acclimation period: at least five days

Diet: fresh Purina Rat Chow No. 5012, *ad libitum*

Water: *ad libitum*

Housing: individually in suspended wire cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS1. In life dates

Start: April 23, 1999; end: May 7, 1999

2. Animal assignment and treatment

The study was conducted as a limit test. Following an overnight fast, five rats/sex were given a single 2000 mg/kg dose of the test material by gavage. The animals were observed for clinical signs of toxicity at 1, 2, and 4 hours post dosing and at least once daily for 14 days. Mortality was checked twice daily. They were weighed on study days 0, 7, and 14. All rats were sacrificed and necropsied.



TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
2000	0/5	0/5	0/10

Data taken from p. 7, MRID 44892603.

### 3. Statistics

Calculation of the oral LD<sub>50</sub> was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

No animals died during the study.

The oral LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg. This places Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 in TOXICITY CATEGORY III.

### B. CLINICAL OBSERVATIONS

Chromorrhinorhea was noted from three rats and wet anogenital areas were noted from four rats. Some of the rats had one or more of the following clinical signs: emaciation, few feces, nose/mouth area stained red, lethargy, flaccidity, ataxia, diarrhea, soiling of the anogenital area, and dyspnea. Two rats had no clinical signs during the study.

### C. BODY WEIGHT

All rats had normal body weight gains.

### D. NECROPSY

Mottled kidneys were noted in two males and two females. All other rats had normal necropsy.

### E. DEFICIENCIES

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

# DATA EVALUATION REPORT

## HYDROGEN PEROXIDE (ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 112)

STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT (81-2)  
MRID 44892604; DP BARCODE: 258938

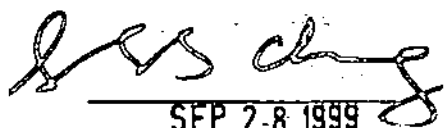
Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

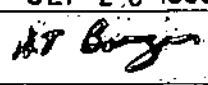
Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K116

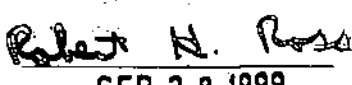
Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: SEP 28 1999

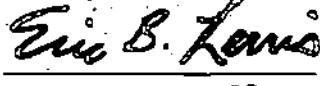
Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature:   
Date: SEP 28 1999

Robert H. Ross, M.S., Group Leader

Signature:   
Date: SEP 28 1999

Quality Assurance:  
Eric Lewis, M.S.

Signature:   
Date: SEP 28 1999

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

HYDROGEN PEROXIDE

Acute Dermal Study (81-2)

EPA Reviewer: Wallace Powell, Ph.D.

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

Date \_\_\_\_\_

Date \_\_\_\_\_

**DATA EVALUATION RECORD**

**STUDY TYPE:** Acute Dermal Toxicity - Rabbit  
OPPTS 870.1200 [§81-2]

**DP BARCODE:** D258938

**P.C. CODE:** 000595

**SUBMISSION CODE:** S567180

**CASE NO.:** 062401

**TEST MATERIAL:** Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide)

**SYNONYMS:** not reported

**CITATION:** Cerven, D.R. (1999) Acute dermal toxicity in rabbits/LD 50 in rabbits. MB Research Laboratories, 1765 Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 99-7513.02, June 22, 1999. MRID 44892604. Unpublished.

**SPONSOR:** Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 44892604) approximately 10% of the body surface area of five male and five female young adult New Zealand White rabbits was dermally exposed to 2000 mg/kg (Limit Test) Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Batch No. 97334) for 24 hours. The animals were observed for 14 days.

One male died within one hour of dosing. One female had few feces on day 6. No other clinical toxicity was noted during the study. Dermal irritation (erythema, edema, and/or flaking skin) was noted on all rabbits at 24 hours through day 14. Two surviving males failed to gain weight during the first week of the study. The body weight gains were normal for the other surviving rabbits. Gross necropsy revealed treated skin abnormalities on eight surviving rabbits.

The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg (Limit Test).

Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III based on the LD<sub>50</sub>.

This acute dermal study is classified as **Acceptable/guideline** and satisfies the Subdivision F guideline requirements for an acute dermal study (81-2) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## 1. MATERIALS AND METHODS

## A. MATERIALS

1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 112

Description: clear light yellow liquid

Lot/Batch #: 97334

Specific gravity: 1.04

Composition: not reported

2. Vehicle and/or positive control

None

3. Test animals

Species: rabbit

Strain: New Zealand White

Age and/or weight at dosing: approximately 12-15 weeks; males: 2.3-2.8 kg, females: 2.1-2.5 kg

Source: Ace Animals, Boyertown, PA

Acclimation period: at least five days

Diet: fresh Purina Rabbit Chow No. 5321

Water: *ad libitum*

Housing: individually in suspended wire cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS1. In life dates

Start: May 5, 1999; end: May 19, 1999

2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rabbits. Animals were given a single 2000 mg/kg dose of Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 applied on top of a gauze patch (10x15 cm) to a clipped area (approximately 10% of the body surface) on the dorsal trunk. The trunk was wrapped with plastic which was secured with tape. The covering was removed 24 hours later and the site washed with distilled water. The test sites were scored for dermal irritation 24 hours after treatment

and on days 7 and 14. The animals were observed for clinical signs of toxicity 1, 2, and 4 hours postdose and once daily thereafter for 14 days. Mortality was checked twice daily. The animals were weighed prior to test material application, and on study days 7 and 14. All rabbits were sacrificed and necropsied.

### 3. Statistics

Calculation of the dermal LD<sub>50</sub> was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

One male died within one hour of dosing.

The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg. This places Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 in TOXICITY CATEGORY III.

### B. CLINICAL OBSERVATIONS

One female had few feces on day 6. No other clinical toxicity was noted during the study. Very slight to moderate erythema was noted on all rabbits at 24 hours and day 7. By day 14, very slight erythema and moderate erythema were noted on one female and one male, respectively. Slight to severe edema was noted on all rabbits at 24 hours. Very slight and slight edema were noted on seven and one rabbits, respectively, by day 7. Two males had very slight edema by day 14. Flaking skin was noted on most of the rabbits by day 7 through day 14.

### C. BODY WEIGHT

Two surviving males failed to gain weight during the first week of the study. The body weight gains were normal for the other surviving rabbits.

### D. NECROPSY

Gross necropsy revealed treated skin abnormalities on eight surviving rabbits.

### E. DEFICIENCIES

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

# DATA EVALUATION REPORT

## HYDROGEN PEROXIDE (ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 117)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (81-4)  
MRID 44892601; DP BARCODE: 258938

Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K116

Primary Reviewer:  
Susan Chang, M.S.

Signature: 

Date: SEP 28 1999

Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: 

Date: SEP 28 1999

Robert H. Ross, M.S., Group Leader

Signature: 

Date: SEP 28 1999

Quality Assurance:  
Eric Lewis, M.A.

Signature: 

Date: SEP 28 1999

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

HYDROGEN PEROXIDE

Primary Eye Irritation Study (81-4)

EPA Reviewer: Wallace Powell, Ph.D.

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

Date \_\_\_\_\_

Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Primary Eye Irritation - Rabbit  
OPPTS 870.2400 [§81-4]

DP BARCODE: D258938

SUBMISSION CODE: S567180

P.C. CODE: 000595

CASE NO.: 062401

TEST MATERIAL: Alphen H<sub>2</sub> Orange 2 Super Concentrate 117 (Hydrogen peroxide)

SYNONYMS: not reported

CITATION: Cerven, D.R. (1999) Acute eye irritation in rabbits. MB Research Laboratories, 1765 Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 98-7280.04, February 22, 1999. MRID 44892601. Unpublished.

SPONSOR: Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44892601) 0.1 mL of Alphen H<sub>2</sub> Orange 2 Super Concentrate 117 (Batch No. 97297) was instilled into the conjunctival sac of three female New Zealand white rabbits. The contralateral eye of the rabbit served as control. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation and on day 7.

Corneal opacity was noted on 1/3 rabbits 24 hours after test material instillation and persisted through 72 hours before resolution by day 7. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by day 7. The test material induced conjunctival redness and chemosis one hour through 72 hours after test material instillation with resolution by day 7. Conjunctival discharge was noted on all rabbits one hour after test material instillation with resolution by day 7. The highest total ocular irritation index was 21.67 recorded 24 hours after test material instillation.

**In this study, Alphen H<sub>2</sub> Orange 2 Super Concentrate 117 was mildly irritating and is in TOXICITY CATEGORY III for primary eye irritation.**

This study is classified as **Acceptable/guideline** and satisfies the Subdivision F guideline requirements for a primary eye irritation study (81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

A. MATERIALS1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 117

Description: clear colorless liquid

Lot/Batch #: 97297

Composition: not reported

2. Vehicle

None

3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: approximately 13-15 weeks; females: 2.0-2.4 kg

Source: Ace Animals, Boyertown, PA

Acclimation period: at least five days

Diet: fresh Purina Rabbit Chow No. 5321

Water: *ad libitum*

Housing: individually in suspended cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS1. In life dates

Start: December 7, 1998; end: December 14, 1998

2. Animal assignment and treatment

The test material (0.1 mL) was instilled into the conjunctival sac of three female rabbits and the eye lids held together briefly. The contralateral eye of each rabbit served as control. The treated eyes of the rabbits were examined with sodium fluorescein at 24, 48, and 72 hours and on day 7. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation and on day 7 according to the Draize method.



## II. RESULTS AND DISCUSSION

- A. Corneal opacity was noted on 1/3 rabbits 24 hours after test material instillation and persisted through 72 hours before resolution by day 7. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by day 7. The test material induced conjunctival redness (grade 1-3) and chemosis (grade 1-4) one hour through 72 hours after test material instillation with resolution by day 7. Conjunctival discharge was noted on all rabbits one hour after test material instillation with resolution by day 7. The highest total ocular irritation index was 21.67 recorded 24 hours after test material instillation.

This classifies the test material as mildly irritating. Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III.

### B. DEFICIENCIES

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

# DATA EVALUATION REPORT

HYDROGEN PEROXIDE  
(ALPHEN H<sub>2</sub> ORANGE<sub>2</sub> SUPER CONCENTRATE 112)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)

MRID 44892602; DP BARCODE: 258938

Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K116

Primary Reviewer:  
Susan Chang, M.S.

Signature: 

Date: SEP 28 1999

Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: 

Date: SEP 28 1999

Robert H. Ross, M.S., Group Leader

Signature: 

Date: SEP 28 1999

Quality Assurance:  
Eric Lewis, M.S.

Signature: 

Date: SEP 28 1999

## Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

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**HYDROGEN PEROXIDE**

Primary Dermal Irritation Study (81-5)

EPA Reviewer: Wallace Powell, Ph.D.

*W. Powell*

\_\_\_\_\_, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

\_\_\_\_\_, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Primary Dermal Irritation - Rabbit  
OPPTS 870.2500 [§81-5]

DP BARCODE: D258938

SUBMISSION CODE: S567180

P.C. CODE: 000595

CASE NO.: 062401

TEST MATERIAL: Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 (Hydrogen peroxide)

SYNONYMS: not reported

CITATION: Cerven, D.R. (1999) Acute dermal irritation in rabbits. MB Research Laboratories, 1765 Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 98-7182.03, February 22, 1999. MRID 44892602. Unpublished.

SPONSOR: Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44892602) six female adult New Zealand white rabbits were dermally exposed on the dorsal trunk to 0.5 mL Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 (Batch No. 97293) for 4 hours. The animals were observed for 72 hours. Irritation was scored by the method of Draize.

No irritation was noted on any rabbit during the study.

**In this study, Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 was not an irritant and is in TOXICITY CATEGORY IV for primary dermal irritation.**

This study is classified as **Acceptable/guideline** and satisfies the Subdivision F guideline requirements for a primary dermal irritation study (81-5) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

**I. MATERIALS AND METHODS**

**A. MATERIALS**

**1. Test material: Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112**

Description: clear light yellow liquid

Lot/Batch #: 97293

Composition: not reported

2. Vehicle

None

3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: approximately 12-17 weeks; males: 2.6-2.9 kg, female: 2.8 kg

Source: Ace Animals, Boyertown, PA

Acclimation period: at least 5 days

Diet: fresh Purina Rabbit Chow No. 5321

Water: *ad libitum*

Housing: individually in suspended wire cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS1. In life dates

Start: October 27, 1998; end: November 6, 1998

2. Animal assignment and treatment

One female and two male animals were given a single 0.5 mL dose of Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 applied under a 2.5x2.5 cm gauze patch on the clipped dorsal trunk. The patch was secured with tape and the trunk was wrapped with plastic in a semi-occlusive manner. The dressings were left in place for 4 hours, after which they were removed and the application sites washed with distilled water. The site was scored for erythema and edema according to the Draize method 60 minutes, 24, 48, and 72 hours after patch removal.

II. RESULTS AND DISCUSSION

## A. No irritation was noted on any rabbit during the study.

Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 was not an irritant and is in TOXICITY CATEGORY IV.

B. DEFICIENCIES

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

SUBMISSION BAR CODE # 8562197REVIEWER TKCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 332DESCRIPTOR Notification of additional unregistered A.I. source

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

4	30	99
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4	30	99
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5	7	99
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METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER \_\_\_\_\_


STATUS \_\_\_\_\_

RESPONSE CODE 10

RESPONSE DATE

MAY 27 1999 ✓ 129

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 27 1999

Alphen LLC  
P. O. Box 19  
Maple Grove Road  
Georgetown, IL 61846

Mailed To: Kyle Sibinovic, Agent For Alphen, Inc.  
Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

RE: EPA Reg. No. 69268-2  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
Your Notification Dated 4/30/99

The Notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add a new supplier for the unregistered active ingredient, is unacceptable for the following reasons.

A. You must submit the request to add an additional unregistered source of active ingredient as a Amendment. As per PR Notice 98-10, Section III, "A registrant may NOT make the following active ingredient related changes by Notification, but must submit an application for Amendment: -A change to an unregistered source of an active ingredient". Include the following in this Amendment.

1. All unregistered sources of active ingredients need a generic data matrix. Therefore, when you submit your Amendment, you must submit a generic data matrix (white and blacked-out copy) for the additional source of hydrogen peroxide. This generic data matrix was not submitted for the original registration, and this was an oversight.

The original formulators Exemption Statement (FES) dated 4/6/98 and the one dated 4/30/99 do not apply, because the FES can only be used with registered sources of active ingredients. Item #2 on the FES clearly explains this restriction.

Even though the Peroxy RED waives all hydrogen peroxide generic data requirements, your matrix must list each guideline series listed in the RED for product chemistry, acute/sub-chronic/chronic toxicology, mutagenicity, ecological effects, fate, etc. You should insert the words "Waived in RED" in the "Submitter" column for each waived study.

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CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2. To show that the new source of hydrogen peroxide is equivalent to the present source, you must submit or cite (on the generic data matrix), the following generic product chemistry studies completed on the additional source: 61-2 (Description of Production Process), 61-3 (Discussion of Impurities), 62-1 (Preliminary Analysis), and 62-2 (Certified Limits). For citations, you should include a copy of any original EPA review which found the study acceptable.

3. You must submit a revised Confidential Statement of Formula listing the name and address of the additional source of hydrogen peroxide.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

*for Tony Kish*

for Marshal Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

**SHALDRA, INC.**  
**4327 REELS MILL RD - FREDERICK, MD 21704-7759**  
**(301) 695-1200 FAX: (301) 695-1409**

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Notification of additional supplier of active ingredient  
H<sub>2</sub>O<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233351  
04-30-1999

Dear Mr. Kish:

Enclosed please find the following:

1. Transmittal letter.
2. Application for Pesticide Notification - OPP ID # 233351.
3. Certification with Respect to Citation of Data.
3. Formulator's Exemption Form.
4. Copy of the MSDS for the new source of the hydrogen peroxide.

The active ingredient, hydrogen peroxide as supplied by the new source is in the same concentration as is the hydrogen peroxide source currently in use, and the additional source will not result in any change to the formula as given in the Confidential Statement of Formula currently on file with the EPA as part of the registration package for this product.

The sponsor believes that the addition of another source of hydrogen peroxide, the active ingredient in this product is a Notification under II. B. 1.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number.

Thank you for your attention to this submission.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, LLC

...

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

233351

## Application for Pesticide - Section I

1. Company/Product Number 69268-2	2. EPA Product Manager M. S. Windell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H <sub>2</sub> O Orange Cone 17	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Cephon LLC PO Box 19 Maple Grove Rd Georgetown, IL 61846 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
active ingredient II.B.1  
Cert attached  
Addition alternate source

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Water Soluble wgt. No. per container	
Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Kyle H. S. Binovic, PhD	Title Agent	Telephone No. (Include Area Code) 801-695-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received 4 (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Kyle H. S. Binovic, PhD	5. Date 04-30-99	133	

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4)).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Formulator's Exemption Statement (EPA Form 8570-27).
4. Five copies of draft labeling.
5. Three copies of any data submitted.
6. Authorization letter where applicable.
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PA Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A - Check the appropriate action for which you are submitting this form.**

**SECTION I -** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II -** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)", "amend the Confidential Statement of Formula by...", "reregistration submission", "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information) -** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point) -** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "major" reregistration, etc.

- 1-5. Self-explanatory.
  6. EPA Use Only.
- 134

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200  
FAX: (301) 695-1409

Re: H2Orange2 Concentrate 117  
EPA Reg. No. 69268-2  
Notification of added active ingredient source and alternate brand name  
OPP ID # 233351

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signed: \_\_\_\_\_

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, LLC

Date: 04-30-1999

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

 401 M Street, S.W.  
 WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Alphen, Div. of Dynachem, P.O. Box 19-Maple Grove Rd. Georgetown, IL 61846 301-695-1200	EPA Registration Number/File Symbol 69268-2
Active Ingredient(s) and/or representative test compound(s) Hydrogen Peroxide	Date 07-29-98
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) 1 Step degreaser, sanitizer, virucide and deodorizer for hard surfaces	Product Name H2Orange2 Concentrate 117

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies' sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies' sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter, (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kyle H. Sibinovic</i>	Date 07-29-98	Typed or Printed Name and Title Kyle H. Sibinovic, Ph.D., Agent
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 07-29-98		EPA Reg No./File Symbol: 69268-22		Page 1 of 1	
Applicant's/Registrant's Name & Address: Alphen, Inc., A Div. of Dynachem P.O. Box 19 - Maple Grove Road, Georgetown, IL 61846		Product: H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient: Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Alphen, Inc.	Own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 117
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			OEL Criteria Document	own	
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
Signature: <i>Kyle H. Sibinovic</i>			Name and Title: Kyle H. Sibinovic, Ph.D., Agent		Date: 07-29-98




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 07-29-98	EPA Reg No./File Symbol: 69268-12	Page 1 of 1			
Applicant's/Registrant's Name & Address: Alphen Inc., A Div. of Dynachem P.O. Box 19- Maple Grove Road, Georgetown, IL 61846		Product: H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient: Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.20 61-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 112
158.20 62-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	69268-R
158.20 63-2 to 21	Product Chemistry	44532001	Alphen, Inc.	own	69268-R
158.135 61-1 to 6	Toxicology	44532004	OEL Criteria Document	PL	
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	own	69268-R
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	own	69268-R
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own	69268-R
158.20 61-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 62-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 63-2 to 21	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
Signature: 	Name and Title: Kyle H. Sibinovic, Ph.D., Agent			Date: 07-29-98	

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United States Environmental Protection Agency  
Washington, DC 20460**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address

Alphon, LLC  
PO Box 19  
Maple Grove Rd  
Georgetown, IL 61846

EPA File Symbol/Registration Number

69268-2

Product Name

H2Orange 2 Concentrate 117

Date of Confidential Statement of Formula (EPA Form 8570-4)

04-06-98

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

Hydrogen Peroxide

(2) Of these, each active ingredient listed in paragraph (1) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Hydrogen Peroxide	[REDACTED]	

\*Product ingredient source information may be entitled to confidential treatment\*

Signature

[Signature]

Name and Title

Kyle N. S. Binadie, PhD

Date

04-30-98

## Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

and to

Office of Management and Budget  
Paperwork Reduction Project (2070-0060)  
Washington, DC 20503





SUBMISSION BAR CODE # 8562204 REVIEWER TK

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69 268-2 PM 33 ACTION CODE 302

DESCRIPTOR Final printed labels

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

4 8 99

4 30 99

5 7 99

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE


OTHER \_\_\_\_\_

STATUS \_\_\_\_\_

RESPONSE CODE 38

RESPONSE DATE MAY 27 1999

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 27 1999

Alphen LLC  
P. O. Box 19  
Maple Grove Road  
Georgetown, IL 61846

Mailed To: **Kyle Sibinovic, Agent For Alphen, Inc.**  
**Shaldra, Inc.**  
**4327 Reels Mill Road**  
**Frederick, MD 21704-7759**

RE: **EPA Reg. No. 69268-2**  
**H<sub>2</sub>Orange<sub>2</sub> Concentrate 117**  
**Your Submission Dated 4/8/99 Containing Final Printed Labels**

This will acknowledge receipt of your final printed labels for **H<sub>2</sub>Orange<sub>2</sub> Concentrate 117**, which were attached to your letter dated 4/8/99. The submitted final printed labels have been placed in your product file. They have neither been reviewed nor stamped in accordance with the PR Notice 82-2.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

*Tony Kish*  
for **Marshall Swindell,**  
**Product Manager Team 33,**  
**Regulatory Management Branch I**  
**Antimicrobials Division (7510C)**

K2

## CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

## CONCENTRATE 117

Alphen: 800-281-9604

### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Alphen H2Orange 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, Alphen H2Orange 117 kills the following viruses in 5 minutes or less at room temperature (20+/-10C): Herpes simplex virus Type 2, Influenza A2/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**1-STEP CLEANING AND SANITIZING:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25o C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen H2Orange 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS).

### SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

### DEODORIZING

For general deodorizing, use 2 part Alphen H2Orange 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen H2Orange 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy, dressing and bag changes, and other spills such as urine or fecal matter, smoke or foot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

### CLEANING SOLUTION DILUTIONS & APPLICATIONS (Dilute with Alphen's Dispensing System Only)

#### LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

#### HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

#### GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

#### SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN AND DOMESTIC ANIMALS

**DANGER.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

### STATEMENT OF PRACTICAL TREATMENT

**In case of CONTACT with product concentrate**

**If in eyes:** Flush immediately with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

### STORAGE AND DISPOSAL

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

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## CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON- FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

### ACTIVE INGREDIENT

Hydrogen peroxide 3.95%

### OTHER INGREDIENTS

96.05%

### TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

## DANGER

### PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-2  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

NOT REVIEWED  
In Accordance with FR Notice 82-2.  
Based on Draft Labeling Dated

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B

**SHALDRA, INC.**  
**4327 REELS MILL RD - FREDERICK, MD 21704-7759**  
**(301) 695-1200 FAX: (301) 695-1409**

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: submission Final Printed Labels  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA Reg. No. 69268-2  
OPP ID# 233346  
04-08-1999

Dear Mr. Kish:

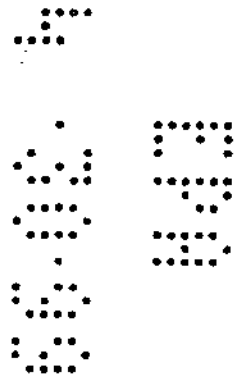
Enclosed please find the required copies of the final printed label for the above referenced product, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2), for inclusion in the product file.

The sponsor, Alphen LLC, wishes to thank you for all your help and assistance with this project, your advice and availability are greatly appreciated.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, LLC



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## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.65 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136) U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). If not exempted by 40 CFR 152.91 (b) (4);
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission, or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A:** Check the appropriate action for which you are submitting this form.

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Method in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Comments Point):** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
  6. EPA Use Only.
- 158

SUBMISSION BAR CODE # 8557280 REVIEWER Tle

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE 322

DESCRIPTOR And - Submitted raw efficacy data  
to confirm its validity as Reg'd in Reg notice item #3

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION  
☐ NON-RESIDENTIAL USE ONLY  
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

9 2 98

9 4 98

9 8 98

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL  
☐ SELECTIVE  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

☐ SUBMITTED  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE 18

RESPONSE DATE MAR 02 1999

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401

"M" St., S.W.

Washington, D.C. 20460

EPA Reg. Number:

69268-2

Date of Issuance:

MAR 02 1999

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

H<sub>2</sub>ORANGE<sub>2</sub>  
CONCENTRATE 117

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Alphen, Inc.  
Division of Dynachem  
P.O. Box 19, Maple Grove Road  
Georgetown, IL 61846

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

The condition of registration included in the original Notice of Registration dated 9/10/98, requiring the submittal of additional efficacy data has been satisfied. This new Notice is being issued to remove the original automatic expiration date imposed upon this registration.

Signature of Approving Official:

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Date:

MAR 02 1999

page 2  
EPA Reg. No. 69268-2

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Enclosure

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(logo)

**H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT  
Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN

**DANGER**

PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-2  
EPA Est. No. 069268-IL-001

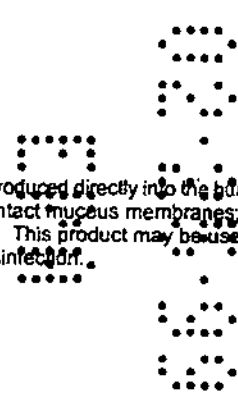
ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes; but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

MAR 02 1999  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**Danger.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

**STATEMENT OF PRACTICAL TREATMENT****In case of CONTACT with product concentrate**

**If in eyes:** Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

**STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

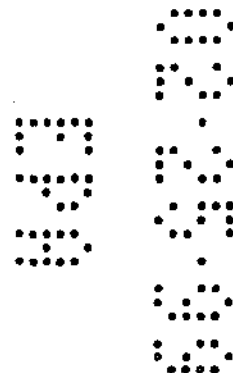
**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 02 1999  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25° C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

**Deodorizing**

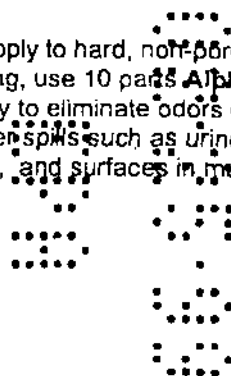
For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 02 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

**LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

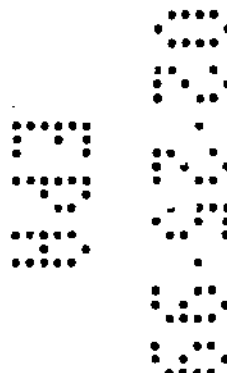
Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 02 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2



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SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

09-02-1998

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 112 - EPA File Symbol: 69268-R  
Response to EPA verbal request for data of 08-31-98  
OPP ID # 233332

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to Mr. Swindell as you now have all the information on both of the Alphen, Inc. Products. In response to conversations between you, and/or Marshall Swindell and myself (08-31-1998), we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233332.)
3. Required Certification with Respect to Citation of Data using the new form.
4. Three copies of Volume 1 - Product Chemistry - H<sub>2</sub>Orange<sub>2</sub> Concentrate 112 - An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces - Revised Sections 61-3, and 63-17, & Section on Identity, Strength, and Purity of Product used in Efficacy Testing. (Raw Data)
5. Three copies of Volume 2 - AOAC Sanitizer Test (for non-food contact surfaces) for Alphen Product 112 - Raw Data (LPI# Alphen 97-10, Presque Isle Cultures).
6. Three copies of Volume 3 - Virucidal Efficacy Testing of Alphen, L.L.C.'s Product 110 Against the Human Immunodeficiency Virus (HIV-1) - Raw Data (LPI# 9268.0, Southern Research)
7. Three copies of Volume 4 - Virucidal Effectiveness Test - Raw Data (LPI# 391-102, Microbiotest)

As instructed, at this time no new labels are included. However, the sponsor will change the signal word to Danger until such time as testing of the above product warrants a change in signal word. At such time as the label review is completed, we will, of course, submit as needed the final labels.

Please let me know directly if you have additional questions regarding this product. Alphen is a very small company and is very anxious to have the registration of the products with at least conditional registrations so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*  
Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

1666

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

Alphen Inc.  
P.O. Box 19  
Georgetown, IL 61846

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

DATE RECEIVED BY EPA

LIST OF SUBMITTED STUDIES:

Volume 1: H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 - An Oxidizing  
Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer.  
MRID: 44646001

Volume 2: AGAC Sanitizer Test (for Non Food Contact Surfaces)  
for Alphen Product 112.  
MRID: 44646002

Volume 3: Virucidal Efficacy Testing of Alphen, L.L.C.'s  
Product 110 Against the Human Immunodeficiency  
Virus (HIV-1).  
MRID: 44646003

Volume 4: Viral Effectiveness Test.  
MRID: 44646004

SEP 10 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

ALPHEN, INC.  
P.O. BOX 19  
GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/03/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

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## MEMO

**To:** Marshall Swindell, PM 33  
**From:** Tony Kish  
**RE:** 69268-2 Raw Data Submitted to Front  
End  
**Date:** 11/9/98

Kyle Sibinovic submitted the raw data, as required in the time limited registration, to the front end and it was date stamped 9/3/98, and given MRID 446460-01 (product chemistry), -02 (sanitizer test), -03 (HIV), and -04 (viruses). Do you have it? We need to log in and send to Srini ASAP as the one year registration clock is ticking (to give them time to contract a study in case we reject any data).

*See next page*

202.0 **Recommendations:**

202.1 **Raw data acceptable:**

1-Reviewed raw data of all three studies and appeared to be acceptable except for the last virucide study against Polio virus II (VR-61) in which the test product failed. However, this virucide activity against polio virus is not claimed on the label.

2- Previous efficacy review recommendations concerning label corrections have not been amended.

EFFICACY AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - I

In: 10/19/98 Out: January 14, 1998  
Reviewed by: Ibrahim Barsoum Date: January 13, 1998  
EPA Reg. No.: 69268-1  
DP Barcode: D250216  
EPA Petition No.: none ~~PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED~~  
Date Division Received: 9/4/98  
Type Product: Cleaner, Sanitizer, Virucide, and deodorizer  
MRID No.: 44646-1, 44646-2, 44646-3, 44646-4  
Product Manager: Marshall Swindell  
PM Team Reviewer: Tony Kish  
Product Name: H2 Orange2 Super Concentrate 112  
Company Name: Alphen, Inc.  
Submission Purpose: Submission of raw data of previously submitted efficacy data.  
Type Formulation: Liquid  
Active Ingredients:  
Hydrogen Peroxide [REDACTED] ... 7.95%

~~PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED~~

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**RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH**

**ANTIMICROBIAL DIVISION**

**EFFICACY REVIEW - II**

EPA Reg. No.: 69268-1  
DP Barcode: D250216  
EPA Petition No.: none  
Date Division Received: 9/4/98  
Type Product: Cleaner, Sanitizer, Virucide, and deodorizer  
MRID No.: 44646-1, 44646-2, 44646-3, 44646-4  
Product Manager: Marshall Swindell  
PM Team Reviewer: Tony Kish  
Product Name: H2 Orange2 Super Concentrate 112  
Company Name: Alphen, Inc.

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200.0 **Introduction:**

200.1 **Uses:**

200.2 **Background Information:** Raw data of previously submitted efficacy results.

201.0 **Data Summary:** None

201.1 **Abstract of Test Reports:** None

201.2 **Brief Description of Test:**

Raw data are provided to support the efficacy of the product as a non-food contact Sanitizer and as a Virucide. Characterization data (identity, purity, strength, and composition of test substances) to verify that the efficacy data were developed at the proper concentrations are also provided.

201.3 **Data Summaries:** None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.



SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

09-02-1998

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange, Concentrate 112 - EPA File Symbol: 69268-R  
Response to EPA verbal request for data of 08-31-98  
OPP ID # 233332

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to Mr. Swindell as you now have all the information on both of the Alphen, Inc. Products. In response to conversations between you, and/or Marshall Swindell and myself (08-31-1998), we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233332.)
3. Required Certification with Respect to Citation of Data using the new form.
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5. Three copies of Volume 2 - AOAC Sanitizer Test (for non-food contact surfaces) for Alphen Product 112 - Raw Data (LPI# Alphen 97-10, Presque Isle Cultures).
6. Three copies of Volume 3 - Virucidal Efficacy Testing of Alphen, L.L.C.'s Product 110 Against the Human Immunodeficiency Virus (HIV-1) - Raw Data (LPI# 9268.0, Southern Research)
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I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerely yours,

*Kyle H. Sibinovic, Ph.D.*

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

*This raw data was required by the  
Reg. Notice dated 9/10/98. It is  
being reviewed under 69268-~~A~~ ~~for~~  
and applies to 69268-~~D~~ also.  
(see 8550002)*

*Tony Kish  
11/19/98*

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TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

Alphen Inc.  
P.O. Box 19  
Georgetown, IL 61846

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

DATE RECEIVED BY EPA

LIST OF SUBMITTED STUDIES:

Volume 1: H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 - An Oxidizing  
Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer  
MRID: 44646001

Volume 2: AOAC Sanitizer Test (for Non Food Contact Surfaces)  
for Alphen Product 112.  
MRID: 44646002

Volume 3: Virucidal Efficacy Testing of Alphen, L.L.C.'s  
Product 110 Against the Human Immunodeficiency  
Virus (HIV-1).  
MRID: 44646003

Volume 4: Viral Effectiveness Test.  
MRID: 44646004

AUG 6 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

ALPHEN, INC.  
P.O. BOX 19  
GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/30/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

176

DISREGARD THIS SUBMISSION

SUBMISSION BAR CODE # 5550000

REVIEWER T Kish

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 69268-E PM 33 ACTION CODE 362

DESCRIPTOR Corrected CSF & Labels

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

07 29 98

09 04 98

09 08 98

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

RESPONSE DATE

11/9/98  
T Kish

177

It was incorrectly reviewed twice by Chem staff

33

This is an ACCEPTED submission.

One copy of the PPC diagnosis and one copy of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a PARTIALLY ACCEPTED / COMPLETELY REJECTED submission.

A copy of the PPC diagnosis and the annotated bibliography are provided for your files. A second copy is provided for your use in corresponding with the original submitter.

[TK-362]

Send New CSF + label  
to Chem

178

At,

Keep the CSF and send  
with the package to

Chenoweth. Everything

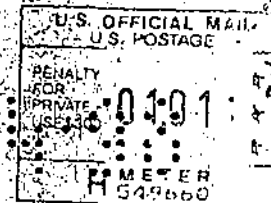
looks OK

Ward

PA

United States  
Environmental Protection  
Agency  
Washington, DC 20460

Official Business  
Penalty for Private Use



United States  
Environmental Protection  
Agency  
Washington, DC 20460  
Official Business  
Penalty for Private Use  
\$300

7510W

Kyle H. Sbinovic, Agent  
Shaldra, Inc.

4327 Reels Mill Rd.  
Frederick, MD 21704-7759

EPA Form 1320-3 (Rev. 3-84)

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DP BARCODE: D250213

CASE: 062401  
SUBMISSION: S550000

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 10/08/98  
Page 1 of 1

\*\*\* CASE/SUBMISSION INFORMATION \*\*\*

CASE TYPE: REGISTRATION ACTION: 362 AmD-TECH FORM CHG AMEND  
CHEMICALS: 000595 Hydrogen peroxide

3.9800%

ID#: 069268-00002 H2 Orange Super Concentrate 117

COMPANY:

PRODUCT MANAGER: 33 MARSHALL SWINDELL

703-308-6341

ROOM: CS1

6B

PM TEAM REVIEWER: TONY KISH

703-308-9443

ROOM: CS1

3W69

RECEIVED DATE: 09/04/98

DUE OUT DATE: 12/03/98

\*\*\* DATA PACKAGE INFORMATION \*\*\*

DP BARCODE: 250213 EXPEDITE: N DATE SENT: 10/08/98 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

DP TYPE: 001

CSF: Y

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 11/22/98

DIV : AD

09/04/98

/ /

NEGOT DATE: / /

BRAN: EASSB

10/15/98

/ /

PROJ DATE: / /

SECT: CTT

10/21/98

/ /

REVR :

Anna

/ /

/ /

CONTR:

Anna Skapich

/ /

/ /

10-23-98

\*\*\* DATA REVIEW INSTRUCTIONS \*\*\*

Please review the attached chemistry data for acceptability.

\*\*\* DATA PACKAGE EVALUATION \*\*\*

No evaluation is written for this data package

\*\*\* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \*\*\*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number  
233313

## Application for Pesticide - Section I

1. Company/Product Number <b>69268-E</b>	2. EPA Product Manager <b>Marshall Swindell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>H2 Orange 2 Concentrate 117</b>	PMS <b>33</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Alphen Division of DynaChem PO Box 19 - Maple Grove Georgetown, IL 61841</b> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. <b>69268-R</b> Product Name <b>H2 Orange 2 Super Conc. 117</b>

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <b>7-22-98</b>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

*Response to EPA letter 07-22-98 to include corrected CSF Label, verified information and new Certification with respect to Citation of Data + Data matrix*

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other			

## Section - IV

1. Contact Point. (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>Kyle H. Sibinovich, PhD</b>	Title <b>Agent</b>	Telephone No. (include Area Code) <b>301-695-1200</b>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <b>182</b>
2. Signature <i>[Signature]</i>	3. Title <b>Agent</b>	
4. Typed Name <b>Kyle H. Sibinovich, PhD</b>	5. Date <b>07-29-98</b>	

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange, Concentrate 117  
EPA File Symbol: 69268-E  
Corrected response to EPA letter of 07-22-98  
OPP ID # 233313  
09-02-1998

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to Ms. Pam Hasty as you now have all the information on both of the Alphen, Inc. Products. In response to that letter of 07-22-98 we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233313).
3. Copy of the CSF corrected to indicate the proper name of the product and of the [REDACTED] as well as the verified pounds per gallon of this product. There are no other changes in the CSF.
4. Required Certification with Respect to Citation of Data using the new form.
5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.
6. Copy of letter from Patrick Stewart explaining the origins of the name of the products.
7. Three copies of Volume 1 - Product Chemistry - H<sub>2</sub>Orange, Concentrate 117 - An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces - Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17, and with a corrected Statement of NO Data Confidentiality.
8. Five copies of the label with the name adjusted to be identical to the name of the product on the CSF, and the signal word changed to "Danger".

We now understand that you have all the required data for [REDACTED] the toxicology and efficacy MRIDs have just had the reviews completed under EPA File Symbol 69268-R, and the information needed for these reviews are included in the submission for 69268-R.

I am also enclosing a copy of the Front-End response sheet and the postmark on the envelope as again there was an extremely lengthy delay in sending the response out after the letter was written. It is this type repeated delay that forces Sponsor's to develop extremely high blood pressure and to feel that their particular project(s) are being ignored or set aside by the Agency.

Please let me know directly if you have additional questions regarding this product. Alphen is a very small company and is very anxious to have the registration of the products with at least conditional registrations so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerely yours,

*Kyle H. Sibinovic*

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

\*Inert ingredient information may be entitled to confidential treatment\*

B3

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division  
DP Barcode D250213 Reg. No. or File Symbol 69268-2  
Manufacturing-Use [ ] OR End-Use Product [ ]

TO: Marshall Swindell/Tony Kisk  
PM Team No. 33

FROM: Anna Skapars, Chemist  
Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief  
Efficacy and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Revised Confidential Statement of Formula dated 7-29-98 is in compliance with PR Notice 91-2, it agrees with the label and CSF is acceptable.

Provided product chemistry data for Guideline Series 61-3 discussion of formation of impurities and Series 63-17 Storage and stability data in M.R.I.D No. H46459-01 are acceptable. These data are in compliance with 40 CFR part 158.155 through 158.190 and it satisfies product chemistry data for this product including the data for Series 61-3 and 63-17.

*\*Confidential Statement of Formula may be entitled to confidential treatment\**

FRONT PANEL - ALPHEN 117

MASTER LABEL

09-08-98

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

**DANGER**

### PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

NET WEIGHT:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

#### **Statement of Practical Treatment**

**Danger.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

#### **In case of CONTACT with product concentrate**

**If in eyes:** Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

#### **STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25° C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

**LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**Deodorizing**

For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

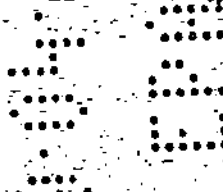
189





**Alphen**

Division of DynaChem, Inc.



# Memo

To: Kyle Sibinovic, Ph.D.  
From: Patrick Stewart  
Date: 07/28/98  
Re: H<sub>2</sub>Orange<sub>2</sub> trade name

---

We "coined this product name in early 1997 and have been using it on our product labels, literature and trade advertising since that time. We have applied for trademark on both the name and the name with our logo. To my knowledge we have never had any comment concerning confusion as a result of the product name.

Thanks

Alphen, Inc.  
A Division of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846  
(217) 662-2130  
FAX: (217) 662-2268

## VOLUME 1

STUDY TITLE: PRODUCT CHEMISTRY - H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 - An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces

TEST ARTICLE: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117

Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17

DATA REQUIREMENTS: 40 CFR 158 GUIDELINES

AUTHOR: KYLE H. SIBINOVIC, Ph.D., SHALDRA, INC., for Alphen, Inc.

LABORATORY PROJECT #: Alphen-98-PC-02

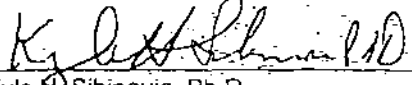
SUBMITTED TO:  
Alphen, Inc., a Div. Of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846

Attn: Patrick Stewart

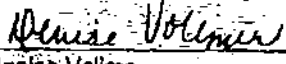
SUBMITTED BY:  
Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759  
and  
Alphen, Inc., a Div. Of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846

  
Patrick Stewart  
Sponsor/Submitter


7-29-98  
Date

  
Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

7-29-98

  
Denise Vollmer  
Regulatory Affairs/Quality Assurance

7-29-98  
Date

  
Bryan Bodart  
Study Director

7-29-98  
Date





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	07-29-98	EPA Reg No./File Symbol	69268-E	Page 1 of 1
Applicant's/Registrant's Name & Address Alphen Inc., A Div. of Dynachem P.O. Box 19- Maple Grove Road, Georgetown, IL 61846		Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117		
Ingredient Hydrogen Peroxide				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note
158.20 61-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 117
158.20 62-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own 69268-R
158.20 63-2 to 21	Product Chemistry	44532001	Alphen, Inc.	own 69268-R
158-135 81-1 to 6	Toxicology	44532004	OEL Criteria Document	PL
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	own 69268-R
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	own 69268-R
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own 69268-R
158.20 61-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own 69268-E
158.20 62-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own 69268-E
158.20 63-2 to 21	Product Chemistry	44582301	Alphen, Inc.	own 69268-E
Signature	Name and Title Kyle H. Sibinovic, Ph.D., Agent			Date 07-29-98

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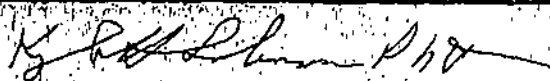


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE, Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 07-29-98		EPA Reg No./File Symbol: 69268-E		Page 1 of 1	
Applicant's/Registrant's Name & Address: Alphen, Inc., A Div. of Dynachem P.O. Box 19-- Maple Grove Road, Georgetown, IL 61846		Product: H <sub>2</sub> O Orange <sub>2</sub> Concentrate 117			
Ingredient: Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Alphen, Inc.	Own	H <sub>2</sub> O Orange <sub>2</sub> Super Concentrate 112
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			OEL Criteria Document	own	
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
Signature: 			Name and Title: Kyle H. Sibinovic, Ph.D., Agent		Date: 07-29-98



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate on any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Alphen, Inc., Div. of Dynachem, P.O. Box 19-Maple Grove Rd. Georgetown, IL 61846 301-695-1200	EPA Registration Number/File Symbol 69268-E
Active Ingredient(s) and/or representative test compound(s) Hydrogen Peroxide	Date 07-29-98
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) 1 Step degreaser, sanitizer, virucide and deodorizer for hard surfaces	Product Name H2Orange2 Concentrate 117

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to fill out this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input checked="" type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
---	--

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kyle H. Sibinovic, PhD</i>	Date 07-29-98	Typed or Printed Name and Title Kyle H. Sibinovic, PhD, Agent
--	------------------	--

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List of companies sent offers of compensation from the Data Submitters List

Active ingredient: Hydrogen peroxide Chemical Id# 000595

1. Company # 063394

Antimicrobial Exposure Assessment Task Force  
2501 M St., NW  
Washington, DC 20037

Data submitted:

Other Data - not specified

2. Company # not given

CSMA  
1800 Wilson Blvd  
Arlington, VA 22209  
Acute Toxicology  
Other Data

Data submitted:

SUBMISSION BAR CODE # 8547637

REVIEWER

P. HaseyCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-E PM 33 ACTION CODE 173

DESCRIPTOR

Confidential Info. on Alphen Product

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM-RECEIVE DATE

07	30	98
----	----	----

07	30	98
----	----	----

07	30	98
----	----	----

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE-ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

18

RESPONSE DATE

SEP 10 1998

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United States Environmental Protection Agency  
Washington, D.C. 20460

Office of Prevention, Pesticides and Toxic Substances  
Office of Pesticide Programs  
Antimicrobial Division

FAX Number (703) 308-6467

**FACSIMILE REQUEST/COVER SHEET**  
(Please type or print clearly in black ink only)

**SEND FAX TO:**

Name: Kyle Sibinovic

Office: \_\_\_\_\_

FAX Phone No. 301-695-1409

Office Phone No. \_\_\_\_\_

**FROM:**

Name: Tony Kish

Division/Branch: \_\_\_\_\_

Office Phone No. \_\_\_\_\_

Office Room No. \_\_\_\_\_

Mail Code: \_\_\_\_\_

Date: 9/10/98

Time: \_\_\_\_\_

Number of pages (with this cover sheet): 13

Special Message: Registration notices for EPA Reg # 69268-R and 69268-E. Please note that Alphen is responsible for offering compensation not only to companies on the data submitters list, but also to companies responsible for studies (eg fish & wildlife) listed in the REID for H<sub>2</sub>O<sub>2</sub>. Your client must do this because H<sub>2</sub>O<sub>2</sub> is an unregistered source of active ingredient. Alphen must offer compensation to any other companies it knows to hold relevant data on H<sub>2</sub>O<sub>2</sub>.

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401

"M" SL, S.W.

Washington, D.C. 20460

EPA Reg. Number:

69268-2

Date of Issuance:

SEP 10 1998

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

H<sub>2</sub>ORANGE<sub>2</sub>  
CONCENTRATE 117

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Alphen, Inc.  
Division of Dynachem  
P.O. Box 19, Maple Grove Road  
Georgetown, IL 61846

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase EPA Registration Number "EPA Reg. No. "69268-2".

Signature of Approving Official:

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Date:

SEP 10 1998

page 2

EPA Reg. No. 69268-2

3. This conditional registration will expire automatically in exactly 12 months (365 calendar days) from the date stamped on this Notice of Pesticide Registration unless you meet the condition stated below. If you fail to satisfy this condition imposed in the registration, EPA may issue a Notice To Cancel under section 6(e) of FIFRA.

You must submit three copies of: (a) raw data from all the efficacy studies that were submitted for review, and (b) characterization data (identity, strength, purity, and composition of test substances for lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054). If EPA verifies and accepts (within the 12 month time restriction) that the efficacy data were developed at the proper concentrations, then a conditional registration can be issued without the 12 month time limitation.

4. Increase the type size of the Signal Word "DANGER" to conform to the latest edition of the EPA Label Review Manual.

5. Move the "Statement of Practical Treatment" boldfaced heading so that it is flush left, and just before "In case of CONTACT with product concentrate".

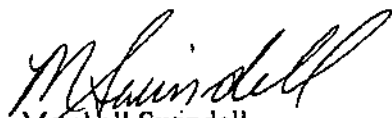
6. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Enclosure

202

FRONT PANEL - ALPHEN 117

MASTER LABEL

09-08-98

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

**OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES**

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

**KEEP OUT OF REACH OF CHILDREN**

### **DANGER**

### **PRECAUTIONARY STATEMENTS**

**SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 069268-  
EPA Est. No. 069268-IL-001

**ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846**

**NET CONTENTS: 1 gallon**

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**SEP 10 1998**

*Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.*

*69268-2*

**NET WEIGHT:**

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

#### **Statement of Practical Treatment**

**Danger.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.**

#### **In case of CONTACT with product concentrate**

**If in eyes:** Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

#### **STORAGE AND DISPOSAL**

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

**LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED (bottle or label)**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**Deodorizing**

For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 10 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69268-2

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EFFICACY AND SCIENCE SUPPORT BRANCH

EFFICACY REVIEW - I

ANTIMICROBIAL DIVISION

IN 06/16/98 OUT 08/21/98

69268-E (4% A.I.  $H_2O_2$  based  
on the -R data)

Srinivas Gowda

Reviewed by Srinivas Gowda Date 08/21/98

EPA Reg. No. or File Symbol 69268-R (8% A.I.  $H_2O_2$ )

LAN Code \_\_\_\_\_

EPA Petition or EUP No. None

Date Division Received 05-20-98

Type Product Non-Food Contact Surface Sanitizer

MRID No (s) 445320-02, 445320-03, and 445601-01

Product Manager PM 31 (MSwindell)

PM Team Reviewer Tony Kish

Product Name H<sub>2</sub>ORANGE, SUPER CONCENTRATE 112

Company Name ALPHEN, INC.

Submission Purpose New Application

Type Formulation Liquid

Active Ingredient (s): 8

Hydrogen peroxide.....7.95

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EFFICACY AND SCIENCE SUPPORT BRANCH

EFFICACY REVIEW - II

ANTIMICROBIAL DIVISION

EPA Reg. No. or File Symbol 69268-R  
LAN Code \_\_\_\_\_  
EPA Petition or EUP No. None  
Date Division Received 05-20-98  
Type Product Non-Food Contact Surface Sanitizer  
MRID No (s) 445320-02, 445320-03, and 445601-01  
Product Manager PM 31 (MSwindell)  
PM Team Reviewer Tony Kish  
Product Name H<sub>2</sub>ORANGE<sub>2</sub> SUPER CONCENTRATE 112  
Company Name ALPHEN, INC.

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## 202.0 Recommendations

### 202.1 Efficacy Supported by the Data:

The submitted data by the Modified EPA's Sanitizer Test Method appear adequate to support effectiveness of the product as a non-food contact surface sanitizer against Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Klebsiella pneumoniae ATCC 4352, Escherichia coli ATCC 25922, and Streptococcus faecalis 19433 and when used at a concentration of 1450 ppm hydrogen peroxide on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against HIV-1(AIDS virus) when tested at 2.710 g. concentrate + 997.3 g of 415.6 ppm synthetic hard water and 2.778 g. concentrate + 997.2 g of 415.6 ppm synthetic hard water dilutions on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 5 minutes at 21°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Herpes simplex virus Type II ATCC VR-734 and Influenza A<sub>2</sub> /Japan/305/57, ATCC VR-100 when tested at a concentration of 500 ppm hydrogen peroxide (13.889 ml. product + 986.111 ml. sterile deionized water) on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at 20°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

### 202.2 Additional Data/Information Required to Support Efficacy:

- a. Submit raw data of all three studies.
- b. Submit characterization data (identity, strength, purity, and composition of test substances, lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054) to verify if the efficacy data were developed at the proper concentrations.

### 203.0 Labeling:

The proposed product name "H<sub>2</sub>ORANGE<sub>2</sub> SUPER CONCENTRATE 112" is not acceptable. Propose another name.

On the Front Panel:

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a. delete "...1-STEP CLEANER..." because the sanitizing data were not developed in the presence of 5% blood serum to support one-step sanitizing claim.

b. "Virucide" claim must be keyed by a symbol to the paragraph listing the tested viruses. Therefore, change "...VIRUCIDE..." to "...VIRUCIDE\*...".

c. Change "...HARD SURFACES..." to read "...HARD NON-POROUS SURFACES..."

On the Right Panel change "1-Step Cleaning and Sanitizing:" to read "For Cleaning and Sanitizing:", and change "...thoroughly clean the surface, allow to air dry" to read "...thoroughly clean the surface, then apply same solution to the surface to sanitize, allow to remain wet for 5 minutes and air dry."

On the Back Panel change "...kills 99.99..." to read "...kills 99.9%..."

On the Back Panel change "...Herpes 2..." to read "...Herpes simplex Type 2..."

**SHALDRA, INC.**  
**4327 REELS MILL RD - FREDERICK, MD 21704-7759**  
**(301) 695-1200 FAX: (301) 695-1409**

Tony Kish  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

09-09-1998

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA File Symbol: 69268-E  
Response to EPA verbal request of 09-08-98 for labels  
OPP ID # 233334

Dear Mr. Kish:

As requested in our discussion regarding the Master Label for the above referenced product, we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233334).
3. Five (5) copies of the Master Label corrected in accordance with your instructions.

Please let me know directly, if you have additional questions or changes regarding this product. The Sponsor greatly appreciates your assistance with this project.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the registration letter as quickly as possible.

Thank you for your assistance with this Application.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

233334

## Application for Pesticide - Section I

1. Company/Product Number 69268-E	2. EPA Product Manager Mr. Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H2Orange2 Concentrate 117	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Alphen, Inc., a Div. of Dynachem Maple Grove Road Georgetown, IL 61846	6. Expedited Review: In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	
<input type="checkbox"/> Check if this is a new address		

## Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input checked="" type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Master Labels corrected in accordance with verbal instructions given on 09-08-98.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
Certification must be submitted. If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Nat Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kyle H. Sabinovic, Ph.D.	Title Agent	Telephone No. (Include Area Code) 301-695-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	212
4. Typed Name Kyle H. Sabinovic, Ph.D.	5. Date 09-09-98	

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). If not exempted by 40 CFR 152.81 (b) (4);
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Metrics where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11-inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended, reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A - Check the appropriate action for which you are submitting this form.**

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify);", "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point):** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

CB

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division

DP Barcode

Reg. No. or File Symbol 69268-E

Manufacturing-Use [ ]

OR End-Use Product [✓]

TO:

Marshall Swindell / Tony Kish  
PM Team No. 33

FROM:

Anna Skapars, Chemist  
Efficacy and Science Support Branch

THRU:

Michelle Wingfield, Acting Chief  
Efficacy and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Provided chemical identity of [REDACTED]  
and [REDACTED] has been cleared and  
pc codes have been assigned and they may  
be used in this formulation.

Confidential Statement of Formula dated 4-6-98  
complies with PR Notice 91-2 and all ingredients  
in CSF are cleared and CSF is acceptable.

For storage and stability data testing for the active  
ingredient should be done at the beginning of storage  
few times during storage and at the end of  
storage and temperature should be reported.

Anna Skapars  
9-2-98

\*Inert ingredient information may be entitled to confidential treatment\*

# CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)

## REQUEST FORM

*Please Expedite FQPA*

CR# 98-0358

REQUESTOR NAME: Anna Skapais

REQUEST DATE: 9/2/98

TEL: ( ) 308-8326 ORG: \_\_\_\_\_

ROOM: \_\_\_\_\_ MAIL CODE: \_\_\_\_\_

(DIV./BR./SEC.)

### CSF ATTACHED:

- ☒ YES If CSF is attached complete Item A and the chemical name in Item B.  
☐ NO If CSF is not attached complete Items A through C.

### A. INFORMATION REQUIRED:

✓ Check Applicable Category

- ☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)  
☒ Provide PCC for Non-Food Use Inert Ingredient(s)  
☐ Provide PCC for Active Ingredient(s)  
☐ Provide PCC for Dye  
☐ Determine if Fragrance is Acceptable for Use in Formulation  
☐ Other (Describe): \_\_\_\_\_

### B. INGREDIENT INFORMATION:

Ingredient No. 1:

Ingredient No. 2:

Chem. Name: \_\_\_\_\_

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

Ingredient No. 3:

Ingredient No. 4:

Chem. Name: \_\_\_\_\_

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

### C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 69268-E Product Name: H<sub>2</sub>O Orange Super Concentrate 117

Registrant: Alpham Food-Use Pesticide: ☐ YES ☒ NO

Percent in Formulation (For Fragrance/Dyes only): \_\_\_\_\_

### INFORMATION

Ingredient No. 1:

PCC: \_\_\_\_\_

TOL. STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 2:

PCC: \_\_\_\_\_

TOL. STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 3:

PCC: \_\_\_\_\_

TOL. STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 4:

PCC: \_\_\_\_\_

TOL. STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Completed By: LINDA FOX

Date Completed: 08/02/98

215

\*Inert ingredient information may be entitled to confidential treatment\*



Alphen, Inc.  
A Division of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846  
(217) 662-2130  
FAX: (217) 662-2268

VOLUME 1

STUDY TITLE: PRODUCT CHEMISTRY - H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 - An Oxidizing Multipurpose, 1-  
Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard  
Surfaces

TEST ARTICLE: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117

Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17

DATA REQUIREMENTS: 40 CFR 158 GUIDELINES

AUTHOR: KYLE H. SIBINOVIC, Ph.D., SHALDRA, INC., for Alphen, Inc.

LABORATORY PROJECT #: Alphen-98-PC-02

SUBMITTED TO:  
Alphen, Inc., a Div. Of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846

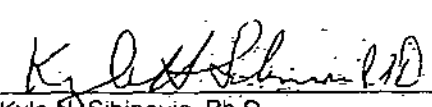
Attn: Patrick Stewart

SUBMITTED BY:  
Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

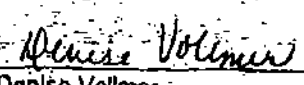
and  
Alphen, Inc., a Div. Of DynaChem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL 61846

  
Patrick Stewart  
Sponsor/Submitter

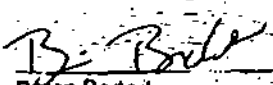
7-29-98  
Date

  
Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

7-29-98

  
Denise Vollmer  
Regulatory Affairs/Quality Assurance

7-29-98  
Date

  
Bryan Bodart  
Study Director

7/29/98  
Date

EPA Reg. NO. 69268-2

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Page \_\_\_\_\_ is not included in this copy.

Pages 217 through 219 are not included in this copy.

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The material not included contains the following type of information:

- \_\_\_\_\_ Identity of product inert ingredients.
- \_\_\_\_\_ Identity of product impurities.
- \_\_\_\_\_ Description of the product manufacturing process.
- \_\_\_\_\_ Description of quality control procedures.
- \_\_\_\_\_ Identity of the source of product ingredients.
- \_\_\_\_\_ Sales or other commercial/financial information.
- \_\_\_\_\_ A draft product label.
- \_\_\_\_\_ The product confidential statement of formula.
- \_\_\_\_\_ Information about a pending registration action.
- ☒ FIFRA registration data.
- \_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_.
- \_\_\_\_\_ The document is not responsive to the request.
- \_\_\_\_\_ Internal deliberative information.
- \_\_\_\_\_ Attorney-Client work product.
- \_\_\_\_\_ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---

SUBMISSION BAR CODE #

5547671

REVIEWER

PH

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO.

69268-E

PM 33

ACTION CODE

123

DESCRIPTOR

Rejected eff date

☐ CHILD RESISTANT PACKAGING☐ CERTIFICATION☐ NON-RESIDENTIAL USE ONLY☐ NOT APPLICABLEREGISTRATION TYPE: ☐ CONDITIONAL☐ UNCONDITIONAL

PROPOSED CLASSIFICATION:

☐ GENERAL☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

07 29 98

07 30 98

08 06 98

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SUBMITTED☐ SELECTIVE☐ NOT SUBMITTED☐ NOT SUBMITTED☐ NOT APPLICABLE☐ NOT APPLICABLE☐ INCORRECT/RESUB☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA

DATE

DUE

DATE

PACK #

SENT

DATE

RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

70

RESPONSE DATE

8/21/98

220



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number  
233313

## Application for Pesticide - Section I

1. Company/Product Number 69268-E	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H <sub>2</sub> Orange 2 Concentrate 117	PM# 33	
5. Name and Address of Applicant (include ZIP Code) Alpha Division of Dynachem PO Box 19 - Maple Grove Georgetown, IL 61841 <input type="checkbox"/> Check if this is a new address	6. Expedited Review: In accordance with FIFRA Section 3(c)(3) (b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. 69268-R Product Name H <sub>2</sub> Orange 2 Super Conc. 117	

## Section II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 7-22-98	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Response to EPA letter of 07-22-98 to include corrected CSF label, verified information and new certification with respect to citation of Data & Data matrix

## Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other			

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kyle H. Sibinovic PhD	Title Agent	Telephone No. (include Area Code) 301-695-1200
2. Signature 		6. Date Application Received (Stamped) 221
3. Title Agent	5. Date 07-29-98	
4. Typed Name Kyle H. Sibinovic PhD		

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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4. **Size(s) of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "major" reregistration, etc.

- 1-5. Self-explanatory.
  6. EPA Use Only.
- 222

FRONT PANEL - ALPHEN 117

MASTER LABEL

03-25-98

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

### **ACTIVE INGREDIENTS**

Hydrogen peroxide	3.95%
-------------------	-------

### **OTHER INGREDIENTS**

96.05%

### **TOTAL**

100.00 %

**KEEP OUT OF REACH OF CHILDREN**

### **CAUTION**

### **PRECAUTIONARY STATEMENTS**

**SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

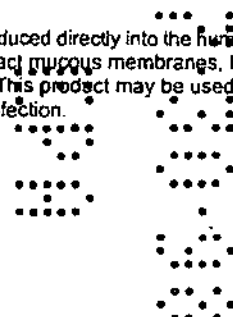
EPA Reg. No. 069268-  
EPA Est. No. 069268-IL-001

**ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846**

**NET CONTENTS: 1 gallon**

**NET WEIGHT:**

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



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**PRECAUTIONARY STATEMENTS****CAUTION****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**  
**KEEP OUT OF REACH OF CHILDREN****STATEMENT OF PRACTICAL TREATMENT**

In case of CONTACT, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If SWALLOWED, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

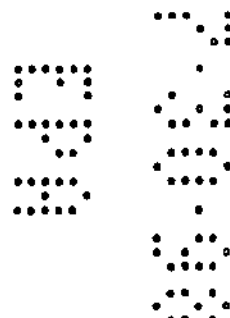
**Caution.** Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.



284

**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

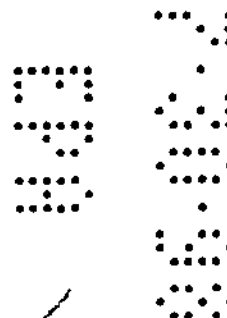
**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A<sub>2</sub>/Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

**To use as a sanitizer and virucide in bathrooms:** Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up.

**HIV-1:** Kills HIV-1 (Human immunodeficiency virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water), in 5 minutes at room temperature (20 - 25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:** Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.





**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

**LIGHT DUTY (1 Oz / gallon ) GREEN**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gallon ) BLUE**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gallon ) RED**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

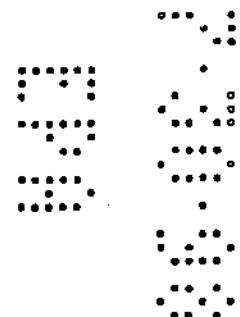
**SUPER DUTY (24-48 Oz / gallon ) PURPLE**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

**Deodorizing**

For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.



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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

 401 M Street, S.W.  
 WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Alphen, Inc., Div. of Dynachem, P.O. Box 19-Maple Grove Rd. Georgetown, IL 61846 301-695-1200	EPA Registration Number/File Symbol 69268-E
Active Ingredient(s) and/or representative test compound(s) Hydrogen Peroxide	Date 07-29-98
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) 1 Step degreaser, sanitizer, virucide and deodorizer for hard surfaces	Product Name H2Orange2 Concentrate 117

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies' sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input checked="" type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies' sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	--

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation, and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kyle H. Sibinovic, PhD</i>	Date 07-29-98	Typed or Printed Name and Title Kyle H. Sibinovic, PhD, Agent
--	------------------	--

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0050

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	07-29-98	EPA Reg No./File Symbol	69268-E	Page	1 of 1
Applicant's/Registrant's Name & Address Alphen Inc., A Div. of Dynachem P.O. Box 19- Maple Grove Road, Georgetown, IL 61846		Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.20 61-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 117
158.20 62-1 to 3	Product Chemistry	44532001	Alphen, Inc.	own	69268-R
158.20 63-2 to 21	Product Chemistry	44532001	Alphen, Inc.	own	69268-R
158-135 81-1 to 6	Toxicology	44532004	OEL Criteria Document	PL	
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	own	69268-R
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	own	69268-R
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own	69268-R
158.20 61-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 62-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 63-2 to 21	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
Signature				Name and Title	Date
				Kyle H. Sibinovic, Ph.D., Agent	07-29-98



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 07-29-98		EPA Reg No./File Symbol 69268-E		Page 1 of 1	
Applicant's/Registrant's Name & Address Alphen, Inc., A Div. of Dynachem P.O. Box 19 - Maple Grove Road, Georgetown, IL 61846		Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117			
Ingredient Hydrogen Peroxide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Alphen, Inc.	Own	H <sub>2</sub> Orange <sub>2</sub> Super Concentrate 117
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			OEL Criteria Document	own	
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-R
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
			Alphen, Inc.	own	69268-E
Signature <i>Kyle H. Sibinovic</i>			Name and Title Kyle H. Sibinovic, Ph.D., Agent		Date 07-29-98

SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Pam Hasty  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA File Symbol: 69268-E  
Response to EPA letter of 07-22-98  
OPP ID # 233313  
07-29-1998

Dear Ms Hasty:

As suggested by Mr. Kish, this letter is directed to you rather than Mr. Swindell as he is away and you are listed as the assigned contact person. In response to that letter of 07-22-98 we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233313).
3. Copy of the CSF corrected to indicate the proper name of the product and of the [REDACTED] as well as the verified pounds per gallon of this product. There are no other changes in the CSF.
4. Required Certification with Respect to Citation of Data using the new form.
5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.
6. Copy of letter from Patrick Stewart explaining the origins of the name of the products.
7. Three copies of Volume 1 - Product Chemistry - H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 -An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces - Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17.
8. Five copies of the label with the name adjusted to be identical to the name of the product on the CSF.

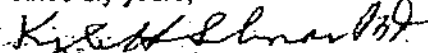
We have been assured by [REDACTED] that they will send the needed data for [REDACTED] to you by today at the latest. The toxicology and efficacy MRIDs are either under review or have just had the reviews completed under EPA File Symbol 69268-R. Mr. Tony Kish of your section is the Registration Specialist assigned the product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112.

Please let me know directly if you have additional questions regarding this product. This is the second of the peroxide products manufactured by Alphen, Inc., and we have been working with the assistance of Dennis Edwards and Marshall Swindell to get them registered at this time as sanitizers, virucides as well as cleaners. Alphen is a very small company and is very anxious to have the registration of the products finalized by early August so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as the Agency has completed review of this submission so that I can arrange to pick up the response. Your letter dated the 22nd of July took a week to travel to Frederick and the Sponsor would rather that time be spent on clearing up any problems.

Thank you for your assistance with this Application.

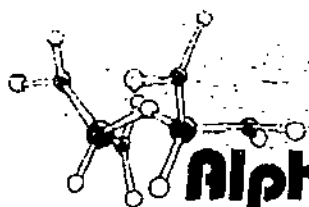
Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

\*Inert ingredient information may be entitled to confidential treatment\*  
\*Product ingredient source information may be entitled to confidential treatment\*

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**Alphen**

Division of DynaChem, Inc.

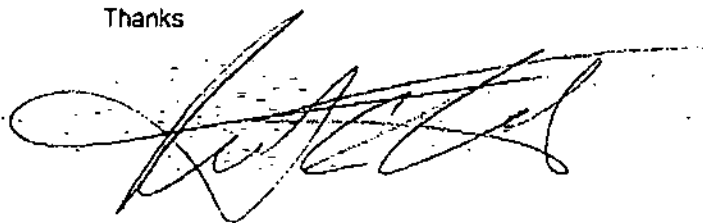
# Memo

**To:** Kyle Sibinovic, Ph.D.  
**From:** Patrick Stewart  
**Date:** 07/28/98  
**Re:** H<sub>2</sub>Orange<sub>2</sub> trade name

---

We "coined this product name in early 1997 and have been using it on our product labels, literature and trade advertising since that time. We have applied for trademark on both the name and the name with our logo. To my knowledge we have never had any comment concerning confusion as a result of the product name.

Thanks



• Page 1

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AUG 6 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

ALPHEN, INC.  
P.O. BOX 19  
GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/30/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

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SHALDRA, INC.  
4327 REELS MILL RD - FREDERICK, MD 21704-7759  
(301) 695-1200 FAX: (301) 695-1409

Pam Hasty  
Registration Specialist  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Application for Pesticide Registration:  
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117  
EPA File Symbol: 69268-E  
Response to EPA letter of 07-22-98  
OPP ID # 233313  
07-29-1998

Dear Ms Hasty:

As suggested by Mr. Kish, this letter is directed to you rather than Mr. Swindell as he is away and you are listed as the assigned contact person. In response to that letter of 07-22-98 we are providing the following:

1. Transmittal letter.
2. Application for Pesticide Registration Form (OPP ID #233313).
3. Copy of the CSF corrected to indicate the proper name of the product and of the [REDACTED] as well as the verified pounds per gallon of this product. There are no other changes in the CSF.
4. Required Certification with Respect to Citation of Data using the new form.
5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.
6. Copy of letter from Patrick Stewart explaining the origins of the name of the products.
7. Three copies of Volume 1 - Product Chemistry - H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 -An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces - Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17.
8. Five copies of the label with the name adjusted to be identical to the name of the product on the CSF.

We have been assured by [REDACTED] that they will send the needed data for [REDACTED] to you by today at the latest. The toxicology and efficacy MRIDs are either under review or have just had the reviews completed under EPA File Symbol 69268-R. Mr. Tony Kish of your section is the Registration Specialist assigned the product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112.

Please let me know directly if you have additional questions regarding this product. This is the second of the peroxide products manufactured by Alphen, Inc., and we have been working with the assistance of Dennis Edwards and Marshall Swindell to get them registered at this time as sanitizers, virucides as well as cleaners. Alphen is a very small company and is very anxious to have the registration of the products finalized by early August so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as the Agency has completed review of this submission so that I can arrange to pick up the response. Your letter dated the 22nd of July took a week to travel to Frederick and the Sponsor would rather that time be spent on clearing up any problems.

Thank you for your assistance with this Application.

Sincerely yours,

*Kyle H. Sibinovic*

Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

*\*Inert ingredient information may be entitled to confidential treatment\**

*\*Product ingredient source information may be entitled to confidential treatment\**

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SUBMISSION CODE # 5545381REVIEWER P. HastyCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 69268-E PM 33 ACTION CODE 172DESCRIPTOR new application for Registration

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION  
☐ NON-RESIDENTIAL USE ONLY  
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONALPROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

06	11	98
----	----	----

06	15	98
----	----	----

06	19	98
----	----	----

## METHOD OF SUPPORT

## FORMULATORS EXEMPTION

☐ CITE-ALL  
☐ SELECTIVE  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

☐ SUBMITTED  
☐ NOT SUBMITTED  
☐ NOT APPLICABLE  
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER


STATUS

RESPONSE CODE

10

RESPONSE DATE

JUL 22 1998

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SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY ✓	AD	EASSE	CTT		
EFFICACY	AD	EASSE	EET		
ACUTE TOX	AD	EASSE	CTT		
RISK TOX	AD	RASSE	TEAM 1		
EXPOSURE	AD	RASSE	TEAM 1		
ENV. FATE	AD	RASSE	TEAM 2		
FISH/WILD	AD	RASSE	TEAM 2		

#### INSTRUCTIONS

Please review Chemistry Data, CDF & Label for acceptability - m.s.d.s is included

#### INSTRUCTIONS

#### INSTRUCTIONS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 22 1998

Alphen  
Division of Dynachem  
P.O. Box 19 - Maple Grove Road  
Georgetown, IL. 61846

Attention: Kyle H. Sibinovic, Ph.D  
Agent for Alphen

Subject: H2Orange2 Super Concentrate 117  
EPA File Symbol No. 69268-E  
Your Application Dated June 11, 1998

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is unacceptable.

The Confidential Statement of Formula dated April 6, 1998 is in compliance with PR Notice 91-2, it agrees with the label and the CSF would be acceptable when all inert ingredients are verified.

The following information should be provided:

1. Your supplier should submit to this Agency the complete chemical composition of [REDACTED] including the chemical name, CAS Reg. No. and the percentage of each component in each product.
2. Please note that based on the Confidential Statement of Formula, the label ingredient statement should declare 3.95% of Hydrogen Peroxide.
3. Please verify the density or pounds per gallon for this product.
4. The label may have only one product name and it must be the same name as in the Confidential Statement of Formula
5. The product name "H2Orange2 Super Concentrate 117" is misleading. Please clarify "H2Orange2" in the product name.

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SYMBOL	7510W						
SURNAME	O. H. Sibinovic						
DATE	7/22/98						

\*Inert ingredient information may be entitled to confidential treatment\*

The submitted product chemistry data in MRID No. 445823-01 for Guideline Ref. No's. 61 and 62 are in compliance with 40 CFR Part 158.155 - 158.180 and the product chemistry data for Guideline Series 63.

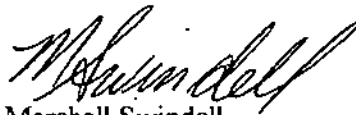
7. For Guideline Ref. No. 63-17, storage and stability, please submit results of 10 months study.
8. Please note that Guideline Ref. No. 61-3 is the discussion of formation of impurities, it is not the discussion of an active ingredient.
9. Please note that you do not qualify for the Formulator's Exemption because you are using an unregistered source of active ingredient.
10. Please note that your Certification with Respect to Citation of Data form is incorrect, option 2 is not applicable since Hydrogen Peroxide is not a new chemical or has exclusive data rights. Also note that under option 3 you neglected to choose a method of support (i.e., Cite-All or Selective).
11. Please indicate if the identified toxicology and efficacy MRIDs have been reviewed and under which registration number they were submitted.

The Agency reserves a full label review until the abovementioned deficiencies are addressed.

This letter does not constitute registration and the product may not be lawfully marketed until the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, please contact Pam Hasty at (703) 303-7933.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division (7510W)

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SHALDRA, INC.  
4327 REELS MILL RD  
FREDERICK, MD 21704-7759  
(301) 695-1200  
FAX: (301) 695-1409

445823-00

Marshall Swindell  
Product Manager 33  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re-Application for Pesticide Registration: H<sub>2</sub>ORANGE<sub>2</sub>  
SUPER CONCENTRATE 117  
EPA File Symbol: 69268-*E*  
OPP ID # 233327  
06-11-1998

Dear Mr. Swindell:

Enclosed please find the following information for the above referenced product:

1. Transmittal letter.
2. Application for Pesticide Registration - OPP ID # 233327.
3. Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation of Data, and Matrix.
4. Three (3) copies of the following:  
Volume 1 - Study Title: Product Chemistry - H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 117 - An oxidizing multipurpose, 1-step cleaner, degreaser, sanitizer (non-food contact surfaces, virucide & deodorizer for hard surfaces. (Alphen 98-PC-02)
5. Five (5) copies of the Proposed Master Label.

44582301

This is the second of a series of products that Alphen, Inc. has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

The reference MRID #S for this submission that were assigned to the first product, EPA File Symbol 69268-R are:

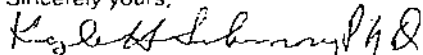
44532001 - Product Chemistry	44532002 - AOAC Sanitizer Test Report
44532003 - HIV Virucidal Test Report	44532004 - Hydrogen peroxide OEL Criteria Document
44560101 - Virucidal Effectiveness Test Report	

The products use hydrogen peroxide as the active ingredient and as a part of the initial submission, the Sponsor included the ECETOC Special Report No. 10 on hydrogen peroxide in place of the acute toxicology and other pertinent information to assist in the registration process for this product. The associated MRID# is as given above.

The Sponsor hopes that the problems encountered with the first submission have now been solved and that both submissions will be considered for rapid approval of their Applications for Pesticide Registration.

If you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

JUN 25 1998

ALPHEN, INC.  
C/O SHALDRA, INC.  
4327 REELS MILL RD  
FREDERICK, MD 217047759

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/15/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

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SHALDRA, INC.  
4327 REELS MILL RD  
FREDERICK, MD 21704-7759  
(301) 695-1200  
FAX: (301) 695-1409

445823-00

Marshall Swindell  
Product Manager 33  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Application for Pesticide Registration: H<sub>2</sub>ORANGE<sub>2</sub>  
SUPER CONCENTRATE 117  
EPA File Symbol: 69268-E  
OPP ID # 233327  
06-11-1998

Dear Mr. Swindell:

Enclosed please find the following information for the above referenced product:

1. Transmittal letter.
2. Application for Pesticide Registration - OPP ID # 233327.
3. Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation of Data, and Matrix.
4. Three (3) copies of the following:  
Volume 1 - Study Title: Product Chemistry - H<sub>2</sub>OOrange<sub>2</sub> Super Concentrate 117 - An oxidizing multipurpose, 1-step cleaner, degreaser, sanitizer (non-food contact surfaces, virucide & deodorizer for hard surfaces. (Alphen 98-PC-02)
5. Five (5) copies of the Proposed Master Label.

44582301

This is the second of a series of products that Alphen, Inc. has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

The reference MRID #S for this submission that were assigned to the first product, EPA File Symbol 69268-R are:


44532001 - Product Chemistry	44532002 - AOAC Sanitizer Test Report
44532003 - HIV Virucidal Test Report	44532004 - Hydrogen peroxide OEL Criteria Document
44560101 - Virucidal Effectiveness Test Report	

The products use hydrogen peroxide as the active ingredient and as a part of the initial submission, the Sponsor included the ECETOC Special Report No. 10 on hydrogen peroxide in place of the acute toxicology and other pertinent information to assist in the registration process for this product. The associated MRID# is as given above.

The Sponsor hopes that the problems encountered with the first submission have now been solved and that both submissions will be considered for rapid approval of their Applications for Pesticide Registration.

If you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

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SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division

DP Barcode D247515  
Manufacturing-Use [ ]

Reg. No. or File Symbol 69268-F  
OR End-Use Product [✓]

TO: Marshall Swindell/Pamela Hasty  
PM Team No. 93

FROM: Anna Skapars, Chemist  
Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief  
Efficacy and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product.

- Confidential Statement of Formula dated 4-6-98 is in compliance with PR Notice 91-2 it agrees with the label and CSF would be acceptable when all inert ingredients are verified.
- B. Ask your Supplier to submit to this Agency complete chemical composition of [REDACTED] including chemical name, CAS Reg. No. and percentage of each component in each product.
- C. Please note that based on Confidential Statement of Formula the label ingredient statement should declare 3.95% of Hydrogen Peroxide.
- Please verify the density or pounds per gallon for this product.
- E. Label may have only one product name and it must be the same name as in Confidential Statement of Formula.
- F. Product name "H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 117" is misleading. Please clarify "H<sub>2</sub> Orange<sub>2</sub>" in the product name.
- G. Submitted product chemistry data in MRID No. 445823-01 for Guideline Ref. No's 61 and 62 are in compliance with 40 CFR part 158.155 - 158.180 and product chemistry data matrix for Guideline Series 63.
- H. For Guideline Ref. No. 63-17 storage and stability please submit results of 10 months study.
- G. Please note that Guideline Ref. No. 61-3 is discussion of 2.9 formation of impurities, it is not discussion of an active ingredient.

Anna Skapars  
7-20-98



PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT ☒ MANUFACTURING-USE PRODUCT ☐  
EPA Reg. No. (or File Symbol No.) 69268-E

Registration ☒

Reregistration ☐  
Case No.: \_\_\_\_\_

DP Barcode/Chemist: D247515 Anna Skapars

1) \_\_\_\_\_ 3) \_\_\_\_\_

2) \_\_\_\_\_ 4) \_\_\_\_\_

1. Product Name: H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 117

2. Company: \_\_\_\_\_

3. Type of Submission: New ☒ Resubmission ☐ Amendment ☐  
"ME-TOO" ☐ Alternate Formulation ☐ REPACK ☐  
Expt Use Permit ☐ Other (Specify) \_\_\_\_\_

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system
  - Are all TGAIs used registered • yes ☐ • no ☐
- Integrated formulation system ☒
- If "ME-TOO", specify EPA Reg. No. of existing product: \_\_\_\_\_

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40CFR§180.1001:

- yes ☐ • no ☐ If yes: • c ☐ • d ☐ • e ☐
- Cleared for non-food use: • yes ☒ • no ☐

4c. Physical state of product: Liquid

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes ☒ • no ☐

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- 4e. Density (or bulk density for solids): at °C. *8.33 lbs/gall*
- 4f. pH (if dissolved or dispersed in water): *3.6*
- 4g. Flash point and/or flame extension: *> 150°F*
- 4h. NCs and CLs are acceptable: • ☒ • not acceptable ☐
- 4i. Active ingredient(s) NC LCL UCL
- A. *Hydrogen Peroxide* *3.95%* *3.83%* *4.07%*
- B.
- C.
- D.
- 4j. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL: • yes ☐ • no ☐ • not applicable ☒
  - All impurities  $\geq 0.1\%$  in the product have been identified: • yes ☐ • no ☐ • not applicable ☒

##### 5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes ☒ • no ☐
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: • yes ☐ • no ☒
  - 1% or more of methyl alcohol: • yes ☐ • no ☒
  - sodium nitrite at any level: • yes ☐ • no ☒
  - a toxic List 1 inert at any level: • yes ☐ • no ☒
  - arsenic in any form: • yes ☐ • no ☒
- 5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
- yes ☐ • no ☐ • not applicable ☒
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
- yes ☒ • no ☐ • not applicable ☐
- 244*

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:      • yes [✓]      • no [ ]

6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):      • yes [ ]      • no [✓]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/Analytical Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix) <sup>1</sup>	A	445823-01
61-2a Manufacturing Process <sup>2</sup>	A	445823-01
61-2b Formulation Method <sup>3</sup>	A	445823-01
61-3 Discussion of Impurities <sup>4</sup>		
62-1 Analysis <sup>5</sup>	A	445823-01
62-2 Certified Limits <sup>6</sup>	A	C.S.F.
62-3 Analytical Method for AIs <sup>7</sup>	A	445823-01

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APA Reg. NO. 69268-2

Page \_\_\_\_\_ is not included in this copy.

Pages 246 through 250 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) \_\_\_\_\_.
- ☐ The document is not responsive to the request.
- ☐ Internal deliberative information.
- ☐ Attorney-Client work product.
- ☐ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

FRONT PANEL - ALPHEN 117

MASTER LABEL

03-25-98

(logo)

## **H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117**

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

ACTIVE INGREDIENTS	
Hydrogen peroxide	3.98%
OTHER INGREDIENTS	96.02%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

### **CAUTION**

### **PRECAUTIONARY STATEMENTS**

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-*E*  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

NET WEIGHT:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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**PRECAUTIONARY STATEMENTS****CAUTION****HAZARDS TO HUMAN AND DOMESTIC ANIMALS****KEEP OUT OF REACH OF CHILDREN****STATEMENT OF PRACTICAL TREATMENT**

In case of CONTACT, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If SWALLOWED, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

**Caution.** Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

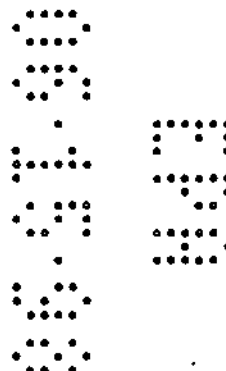
**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

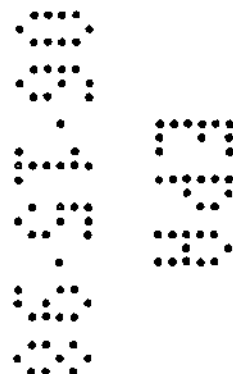
**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A<sub>2</sub>/Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

**To use as a sanitizer and virucide in bathrooms:** Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up.

**HIV-1:** Kills HIV-1 (Human immunodeficiency virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water), in 5 minutes at room temperature (20 - 25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:** Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.



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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

**LIGHT DUTY (1 Oz / gallon ) *GREEN***

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gallon ) *BLUE***

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gallon ) *RED***

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

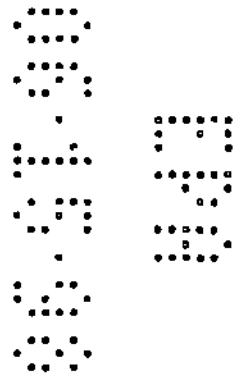
**SUPER DUTY (24-48 Oz / gallon) *PURPLE***

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

**Deodorizing**

For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

06/16/98

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Shaldra, Inc.  
4327 Reels Mill Road  
Frederick, MD 21704-7759

PRODUCT NAME: H2 Orange Super Concentrate 117  
COMPANY NAME: Shaldra, Inc.  
OPP IDENTIFICATION NUMBER: 233327  
EPA FILE SYMBOL: 69268-E  
EPA RECEIPT DATE: 06/11/98

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The office of Pesticides Programs has received your application for a new registration and it passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Marshall Swindell, Product Manager 33 at (703)-308-6341.

Sincerely,

A handwritten signature in cursive script, appearing to read "David L. Jones".

Front End Processing Staff  
Information Resources & Services Division  
Information Services Branch

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SHALDRA, INC.  
4327 REELS MILL RD  
FREDERICK, MD 21704-7759  
(301) 695-1200  
FAX: (301) 695-1409

Marshall Swindell  
Product Manager 33  
Antimicrobial Program Division (7510W)  
US Environmental Protection Agency  
Crystal Mall 2, Room 266A  
1921 Jefferson Davis Hwy  
Arlington, VA 22202

Re: Application for Pesticide Registration: H<sub>2</sub>ORANGE<sub>2</sub>  
SUPER CONCENTRATE 117  
EPA File Symbol: 69268- E  
OPP ID # 233327  
06-11-1998

Dear Mr. Swindell:

Enclosed please find the following information for the above referenced product:

1. Transmittal letter.
2. Application for Pesticide Registration - OPP ID # 233327.
3. Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation of Data, and Matrix.
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Volume 1 - Study Title: Product Chemistry - H<sub>2</sub>OOrange<sub>2</sub> Super Concentrate 117 - An oxidizing multipurpose, 1-step cleaner, degreaser, sanitizer (non-food contact surfaces, virucide & deodorizer for hard surfaces. (Alphen 98-PC-02)
5. Five (5) copies of the Proposed Master Label.

This is the second of a series of products that Alphen, Inc. has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

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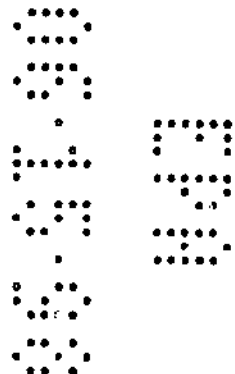
If you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours,



Kyle H. Sibinovic, Ph.D.  
Agent for Alphen, Inc.

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NIFT

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

233327

## Application for Pesticide - Section I

1. Company/Product Number 69268-E	2. EPA Product Manager Marshall Sundell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H <sub>2</sub> Orange 2 Super Concentrate 117	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Alphen, Inc. Maple Grove Rd. Box 19 Georgetown, IL 61846 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 69268-R Product Name H <sub>2</sub> Orange 2 Super Concentrate 112

## Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Pesticide Registration - Product Companion to one already submitted

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 gallon	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Kyle H. Sibinovic, PhD	Title Agent	Telephone No. (Include Area Code) 301-695-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)
2. Signature [Signature]	3. Title Agent		
4. Typed Name Kyle H. Sibinovic, PhD	5. Date 06-11-98	257	

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

### PAPERWORK REDUCTION ACT NOTICE

Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4)).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Formulator's Exemption Statement (EPA Form 8570-27).
4. Five copies of draft labeling.
5. Three copies of any data submitted.
6. Authorization letter where applicable.
7. Matrices where applicable.

**Submission of Labeling:** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data:** Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A:** Check the appropriate action for which you are submitting this form.

**SECTION I:** This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number:** Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager:** If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification:** Specify the proposed classification of this product.
4. **Product Name:** Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant:** The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review:** FIFRA section 3 (c) 3(B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II:** This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission:** Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest, or crop (specify)", "amend the Confidential Statement of Formula by...", "reregistration submission", "general label revision of use directions". Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information):** This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging:** Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container:** Indicate type of container in which product will be marketed.
3. **Location of Net Contents:** Indicate the location of the net contents information for your product.
4. **Size of Retail Container:** Specify the net contents of all retail containers for your product.
5. **Location of Use Directions:** Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product:** Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point):** This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "make do", reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

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United States Environmental Protection Agency  
Washington, DC 20460

## Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address <b>Alphen</b> <b>A Division of Dyna Chem</b>	EPA File Symbol/Registration Number <b>69268-E</b>
	Product Name <b>H2O Orange 2 Super Concentrate</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>04-06-98</b>

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Hydrogen peroxide	[REDACTED]	

\*Product ingredient source information may be entitled to confidential treatment\*

Signature <b>Kyle H. S. Bindovic</b>	Name and Title <b>Kyle H. S. Bindovic, PhD</b>	Date <b>06-11-98</b>
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## Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

and to

Office of Management and Budget  
Paperwork Reduction Project (2070-0060)  
Washington, DC 20503



United States  
Environmental Protection Agency  
Washington, DC 20460

Form Approved  
OMB No. 2070-0080  
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicants Name and Address

Alphen, Inc.  
A Division of Dynachem

EPA File Symbol/Registration Number

69268-E

Product Name H2Orange 2 Super Concentrate 117

Date of Application

06-11-98

**NOTE:** If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study:

☐ I am the original submitter\*, or

☒ I have obtained the written permission of the original submitter for Hydrogen Peroxide <sup>3576</sup> which is  
(insert name of chemical)  
Solvay Interox Inc (for multiple chemicals link the companies who are original data submitters  
(insert names of companies)  
with the appropriate chemical name) to cite that study\*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☐ I am the original data submitter\*, or

☐ I have obtained the written permission of the original data submitter for \_\_\_\_\_ which is  
(insert name of chemical)  
(for multiple chemicals link the companies who are original data submitters  
(insert names of companies)  
with the appropriate chemical name) to cite that study\*, or

b. ☒ I have notified in writing the companies Solvay Interox Inc for Hydrogen Peroxide <sup>(3576)</sup> that  
(insert names of companies) (insert name of chemical)  
have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple  
(insert names of companies) (insert name of chemical)  
chemicals link the companies who are original data submitters with the appropriate chemical name)  
listed on the Pesticide Data Submitters List for all active ingredients contained in my product  
(cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer  
Statement below.)

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple  
(insert names of companies) (insert name of chemical)  
chemicals link the companies who are original data submitters with the appropriate chemical name)  
that have submitted the studies which I have cited (Selective method\*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

\* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature

Kyle H. Sibinovic

Name and Title

Kyle H. Sibinovic, Ph.D. - Agent

Date

06-11-98

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Kyle H. Sibinovic

Name and Title

Kyle H. Sibinovic, Ph.D. - Agent

Date

06-11-98

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Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503; marked "Attention Desk Officer for EPA."



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DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: <u>H2 Orange 2 Super Concentrate 117</u> 5. APPLICANT'S NAME AND ADDRESS: <u>Alphen Inc</u> <u>P.O. Box 19 - Maple Grove Rd</u> <u>Georgetown, IL 61846</u>	2. EPA REG.NO/FILE SYMBOL: <u>69268-E</u> 6. APPLICATION FOR REGISTRATION DATED: <u>06/11/98</u> Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO <u>  </u> 7. NAME OF ACTIVE INGREDIENT(S): <u>Hydrogen Peroxide</u>	4. PAGE <u>1</u> OF <u>4</u>
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8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER	
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. Other (Explain)		
§158.20	PRODUCT CHEMISTRY								
61-1	Identity of ingredients	Y	06-11-98						
61-2	Statement of composition	Y							
61-3	Discussion of formation of ingredients	Y							
62-1	Preliminary analysis	Y							
62-2	Certification of limits	Y							
62-3	Analytical methods for enforcement limits	Y							
63-2	Color	Y							
63-3	Physical state:	Y							
63-4	Odor	Y							
63-5	Melting point	NA							
63-6	Boiling point	NA							
	Density, bulk-density, or								

# DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. <u>H2 O orange 2 Super</u> PRODUCT NAME: <u>Concentrate 117</u>	2. EPA REG.NO/FILE SYMBOL <u>69268-E</u>	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO <u>      </u>	4. PAGE <u>2</u> OF <u>4</u>
5. APPLICANT'S NAME AND ADDRESS <u>Alpha, Inc.</u> <u>PO Box 19 - Maple Grove, IL</u> <u>Georgetown, IL 61846</u>	6. APPLICATION FOR REGISTRATION DATED <u>06/11/98</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): <u>Hydrogen peroxide</u>	

[illegible]

DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. <u>H<sub>2</sub>Oxange 2</u> PRODUCT NAME: <u>Super Concentrate 117</u> 5. APPLICANT'S NAME AND ADDRESS <u>Alphen Inc</u> <u>P.O. Box 19 - Maple Grove Rd</u> <u>Georgetown, IL 61846</u>	2. EPA REG.NO/FILE SYMBOL <u>69268-F</u> 6. APPLICATION FOR REGISTRATION DATED <u>06/11/98</u> Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO <u>      </u> 7. NAME OF ACTIVE INGREDIENT(S): <u>Hydrogen peroxide</u>	4. PAGE <u>3</u> of <u>4</u>
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8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. Other (Explain)	
\$158.20	PRODUCT CHEMISTRY (continued)							
63-20	Corrosion characteristics	✓	06-11-98					
63-21	Dielectric breakdown voltage	NA						
\$158.135	TOXICOLOGY							
81-1	Acute oral LD-50, rat						OEL Criteria	44532004
81-2	Acute dermal LD-50						Document	
81-3	Acute inhalation LC-50, rat							
81-4	Primary eye irritation, rabbit							
81-5	Primary dermal irritation							
81-6	Dermal sensitization							

DATA REQUIREMENT LIST FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: <u>H<sub>2</sub>O Orange 2 Super Concentrate 117</u>	2. EPA REG.NO/FILE SYMBOL <u>69268-E</u>	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO <u>    </u>	4. PAGE <u>4</u> of <u>4</u>
5. APPLICANT'S NAME AND ADDRESS <u>Alphen Inc</u> <u>PO Box 18 - Maple Grove Rd</u> <u>Georgetown, IL 61846</u>	6. APPLICATION FOR REGISTRATION DATED <u>06/11/98</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): <u>Hydrogen peroxide</u>	

[illegible]

FRONT PANEL - ALPHEN 117

MASTER LABEL

03-25-98

(logo)

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

ACTIVE INGREDIENTS	
Hydrogen peroxide	3.98%
OTHER INGREDIENTS	96.02%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

### CAUTION

### PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

NET WEIGHT:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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3333  
2222  
3333  
3333

**PRECAUTIONARY STATEMENTS****CAUTION****HAZARDS TO HUMAN AND DOMESTIC ANIMALS**  
**KEEP OUT OF REACH OF CHILDREN****STATEMENT OF PRACTICAL TREATMENT**

In case of **CONTACT**, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If **SWALLOWED**, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

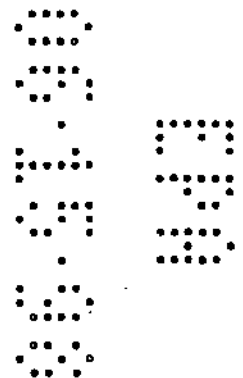
**Caution.** Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.



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**DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

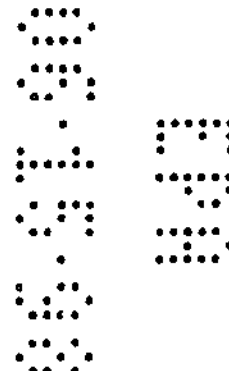
**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A<sub>2</sub>/Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

**To use as a sanitizer and virucide in bathrooms:** Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up.

**HIV-1:** Kills HIV-1 (Human immunodeficiency virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water), in 5 minutes at room temperature (20 - 25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:** Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.



**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

**LIGHT DUTY** (1 Oz / gallon ) **GREEN**

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE** (2 Oz / gallon ) **BLUE**

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY** (10 Oz / gallon ) **RED**

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY** (24-48 Oz / gallon) **PURPLE**

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

**Deodorizing**

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

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